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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(54) Title: UNIVERSAL HIP COMPRESSION DEVICE</b> <b>(54) Titre: DISPOSITIF UNIVERSEL DE COMPRESSION DE LA HANCHE</b>  <b>(57) Abstract</b> <p>A universal osteosynthesis device for fixating femur fractures, the device being in the form of a screw member having a proximal screw thread for compressingly engaging within the femur under axial load provided by a compression nut applied to the distal end of the screw member. The screw member includes an axially shiftable migration device which opens when it is desired to anchor the device within the femur. Extension members are provided further enabling the device to be used with a large range of patients. A locking plate is provided which can be quickly and easily adapted to the particular features of a patient's femur.</p> <b>(57) Abrégé</b> <p>Ce dispositif universel d'ostéosynthèse, qui est destiné à fixer des fractures du fémur, se présente sous la forme d'un élément à vis possédant un filetage proximal venant s'insérer de manière compressive dans le fémur sous l'effet d'une charge axiale fournie par un écrou de compression placé à l'extrémité distale de l'élément à vis. Cet élément à vis comporte dispositif de migration, pouvant se décaler axialement et s'ouvrant, lorsque il est nécessaire, pour ancrer le dispositif dans le fémur. Des éléments auxiliaires sont ajoutés au dispositif, ce qui permet de l'utiliser avec un large éventail de patients. Le dispositif comporte une plaque de blocage pouvant être rapidement et facilement adaptée en fonction des particularités du fémur du patient.</p>		

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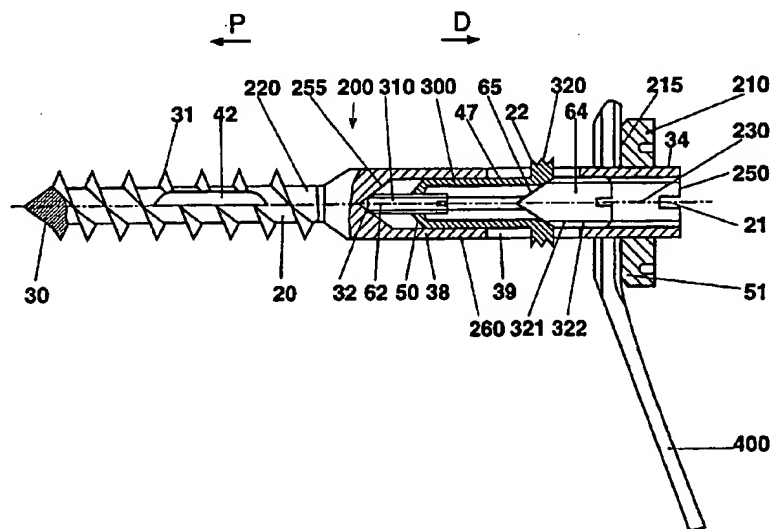
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(54) Title: UNIVERSAL HIP COMPRESSION DEVICE



(57) Abstract

A universal osteosynthesis device for fixing femur fractures, the device being in the form of a screw member having a proximal screw thread for compressingly engaging within the femur under axial load provided by a compression nut applied to the distal end of the screw member. The screw member includes an axially shiftable migration device which opens when it is desired to anchor the device within the femur. Extension members are provided further enabling the device to be used with a large range of patients. A locking plate is provided which can be quickly and easily adapted to the particular features of a patient's femur.

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## Description

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## UNIVERSAL HIP COMPRESSION DEVICE

### Technical Field

The present invention relates to a device for fixating a fractured femur by holding together in compression the fractured portions of the femur. In particular the present invention relates to a universal fixating device that may be adapted to take account of anatomical as well as physiological differences between a range of patients.

### Background

Referring to Figure 1, the general anatomical regions of interest of the femur (1) include the capest or femur head (2), collum or femur neck (3), the Trochanter major (4), Trochanter minor (5), Undertrochanter area (6), Cortical layer (7) and Diafiz (8).

In the present specification, the term proximal (P) refers to a direction towards and into the patient body, while the term distal (D) refers to a direction generally away from the patient body. Thus, referring to Figure 1, the femur may be divided for easy reference into a proximal area and distal area.

Referring again to Figure 1, femur neck fractures may be divided into medial fractures and lateral fractures. Medial fractures include subcapital fractures (9), transcervical fractures (10) and basal fractures (11). Lateral fractures include

5 transtrochanter fractures (12), intertrochanter fractures (13) and  
undertrochanter fractures (14).

10 Broken lines (15), (16), (17) and (18) schematically illustrate the dimensional  
relationship between the distal and proximal areas of the femur in different  
patients. Line (19) represents a reference axis of the femur neck (3).

15 The problem of treating femur neck fractures is of great social importance,  
especially in geriatrics, such fractures occurring more commonly with the  
20 elderly than with other age groups. Such fractures are often caused, particularly  
after age 70, by a relatively light trauma, non-coordinated movements, sharp  
turns, walking, going upstairs, lifting and carrying heavy loads, as due to senile  
25 osteoporosis characteristic of elderly people, wherein the bones become more  
brittle and fragile. Unfortunately femur neck fractures, especially subcapital  
fractures, often knit badly, so that for elderly people they often become a fatal  
30 injury.

In the USA alone, medical statistics estimate 250 thousand femur neck  
fractures annually. 20% of victims die within a year. After a year' treatment  
35 15-20% of patients are still in need of care, with 50% of them suffering from  
aftereffects. \$ 7 billions are annually spent in USA to provide medical care of  
patients with femur neck fractures (H.W. Wahner, 1987).

40 The vast majority of elderly people with femur neck fractures have different  
susceptibility to aging and may also suffer from a number of debilitating  
45 diseases. They also tend to have limited reserves as well as less effective  
immune systems. Even after correct and timely osteosynthesis with elderly and  
old people, nonunion of femur neck fractures and development of femur head  
50 necrosis occurs nearly in 30 % of patients (A.V.Kaplan, 1979).

5 Most of patients in this age group suffer from pronounced osteoporosis.  
Therefore stops such as femur screws or nails are badly fixed in a porous bone.  
10 This often results in a second displacement and nonunion of bone fragments.  
With patients in this age group subcapital femur neck fractures occur most  
frequently, and fragments fixing at osteoporosis appears to be inadequately  
15 stable. Therefore medical practice has been to treat femur neck fractures of  
elderly people with the use of an endoprosthesis. Total replacement of the  
thigh joint in such patients is carried out very seldom because of its  
20 traumatability, hemophilia as well as of osteoporosis and essential operational  
risk. Endoprosthesis at femur neck fractures is performed more often though  
there is a great number of contraindications to its application. It would not be  
25 correct to apply it at all femur neck fractures in elderly patients.

Closed osteosynthesis by means of a special device to treat such fractures  
30 appears to be the most favourable course of action for elderly patients. Even in  
cases where fracture non-union eventually occurs, it can still provide at least  
short-term relief to patients.

35 A number of devices have been proposed for closed osteosynthesis of femur  
neck fractures, such as Richards compression screw system by "Richards  
Manufacturing Co. Inc.", Memphis, Tennessee, USA, (U.S. Pat.  
40 No. 4,095,591, the contents of which are included herein by reference thereto).

45 The compression screw system includes an extension provided for being  
nonrotatably fixed to a lag screw that is to be anchored to the head of a femur  
or other bone in a manner so as to allow compression to be applied to a  
50 fracture. The extension extends outward of the bone when attached to the lag  
screw is anchored to the bone to allow a compression plate to be easily  
55



positioned thereof. The cross section of the extension is substantially the same as the cross section of the lag screw to allow the compression plate to be easily and quickly passed onto the lag screw from the extension once the compression plate has been positioned on the extension.

The Richards system has a number of drawbacks, as follows: a) the bone tissue of the femur head is drilled out over the whole duct length whereby bone tissue (trabeculae) and endosteum is essentially destroyed, and the blood supply which is already insufficient is affected; b) the design of the introduced rod and its inadequately effective thread do not provide a stable compression connection of bone parts. At best bone fragments simply come in contact without a stable mutual fixation. Micromobility of bone fragments is as well possible. c) to position Richards system it is necessary to make a large cut in the femur muscular tissues to locate a compression plate. Thus, the Richards system is inadequate to the task of treating femur neck fractures, especially of subcapital fractures which simply do not knit in most cases.

Since the publication of U.S. Pat. No. 4,095,591 numerous improvements of Richards system have been attempted as described in, for example, U.S. Patent Nos. 4,236,512; 4,432,358; 4,791,918; 4,794,919; 4,964,403; 5,871,485 (1978-1999), Patent of Israel No. 54025 (1978), the contents of which are included herein by reference thereto.

However all the above mentioned devices have similar drawbacks to the Richards system- high traumatability of the femur bone and tissues and inadequate efficiency for the treatment of femur neck fractures, such as medial

5 fractures. The application of the devices disclosed by these patents for the<sup>5</sup>  
treatment of subcapital fractures is simply unsuitable.

10  
There are also known devices developed by "Howmedica International Inc."  
15 (U.S. Pat. No. 5, 176, 681), "Smith & Nephew Richards Inc." (U.S. Pat. No.  
5, 167, 663 and EP 0441577), "Endocare AG" (U.S. Pat. No. 5, 713, 902).  
The contents of these references are included herein by reference thereto.  
20 These devices comprise a rod introduced inside the hip bone and a screw  
attached to this rod to fix the femur neck. The devices are unwieldy, may cause  
traumas to the patient, and their efficacy is on the level of the Richard system  
25 device (do not provide a stable compression connection of bone parts).

30 There is further known an "Osteosynthesis device" disclosed in U.S. Pat. No.  
5,437,674, the contents of which are included herein by reference thereto. An  
osteosynthesis device including a screw whose tip is pyramidal or conical and  
35 whose body is provided, at a distal end thereof, with an outside thread, wherein  
the head of the screw has a plurality of foldable small wings integral with the  
body and wherein the screw has a device for folding the small wings. The  
40 device is useful particularly for fractures of the scaphoid, of the medial  
malleolus, Garden fractures 1 and 2 of the neck of the femur, pertrochanterian  
fractures of the femur, and generally, for fractures of small bones, and for  
45 putting in place hip or shoulder stops.

50 However this device is also inadequately efficient for the treatment of femur  
neck fractures, such as medial fractures. It cannot be used for the treatment of  
subcapital fractures.

5 In SU 938969, the contents of which are included herein by reference thereto,  
an osteosynthesis device for femur neck fractures is disclosed. The device  
10 comprises a rod with a buttress thread on one end and a hold-down nut on the  
other end of the rod having an internal thread. There are also provided tabs  
located in apertures formed in the rod on the side of the hold-down nut and a  
15 mechanism for operating the tabs. The mechanism includes a screw disposed in  
the inner tread of the rod and engaging the tabs.

20 However this device also has some drawbacks. It is not universal as its design  
does not allow for the differences in linear femur neck dimensions with  
different people, different cortical layer thickness in the undertrochanter femur  
area. Furthermore, the tabs are fixed axially with respect to the rod, and  
25 moreover do not enable the anchoring in the bone to be sufficiently secure.  
Therefore such a device must be manufactured individually for each patient or  
in series differing in dimensions according to anthropological parameters of  
30 different patients, so that the axial length of the rod, as well as the precise  
location of the tabs with respect thereto (and therefore to the optimal part of  
the bony tissue in which the tabs should be anchored) may be optimised for  
35 each patient.

40 Furthermore, the device of SU 938969 is unsuitable for treating some types of  
lateral fractures, such as undertrochanter fractures, and therefore unsuitable as  
a universal hip compression device for all kinds of femur neck fractures.

45 Many prior art devices use a rigid pressure or locking plate for supporting a  
femur screw or nail member that is introduced in the femur. Such prior art  
pressure plates are rigidly mounted to the screw member at the distal end  
thereof at a particular angle, and the plate itself is then mounted to the femur  
50 with the aid of a number of nails or wood screws, for example, driven through

5 the plate and into the femur, well below the diafiz. Since the angle between the  
plate and the screw member is fixed, the pressure plate must usually be  
10 mounted to the femur first, and then the screw member implanted into the  
femur neck. As such, depending on the particular type of fractures as well as  
anatomical details of each patient, the angle between these components must  
15 be determined before surgery, and a special pressure plate/screw member  
combination for the patient must be provided in which the angle is irreversibly  
set. A great disadvantage of this type of system is that the angle in which the  
20 screw member must be implanted into the femur must be matched to the angle  
required by the pressure plate, otherwise unwanted stresses are introduced into  
the femur.

25 An object of the present invention is to provide a universal and simple device  
for compression treatment of all kinds of femur neck fractures including medial  
fractures and including both subcapital fractures and lateral fractures, such as  
30 undertrochanter, intertrochanter and transtrochanter fractures.

Another object of the present invention is to provide a device for the fixation of  
35 femur fractures comprising means for reliably anchoring the device in the bone  
with all types of femur neck fractures.

40 It is another object of the present invention to provide a device for the fixation  
of femur fractures enabling the reliable compressive union of bone parts in  
patients with different anthropometric dimensions of femur neck.

45 Another object of the present invention is to provide a fixation device which  
reduces traumatization of a patient's bones and tissues during implantation of  
the device.

50 It is another object of the present invention to provide a universal pressure

5 plate for use with a screw member, either that disclosed herein or indeed with  
any other suitable screw member, in which the angle between the screw  
10 member and the pressure plate may be adjusted and set during the implantation  
procedure.

15 It is another object of the present invention to provide such a fixation device  
that is simple to use.

20 It is another object of the present invention to provide such a fixation device  
that is relatively simple mechanically and thus economic to produce as well as  
to maintain in comparison to prior art devices.

25 The present invention achieves these and other objects by providing a device  
for fixating a fractured femur in which thrust surfaces of a screw thread at the  
proximal end of a screw member together with a compression member to bring  
30 together in compression parts of the fractured femur. An axially movable and  
settable antimigration device anchors the screw member in the bone where  
desired, increasing the versatility and universality of the device. Extension  
members increase the effective axial length of the screw member to take  
35 account of anatomical differences between patients.

40 Further, a two-part pressure plate is provided for use with any suitable screw  
member, in particular the fixating device of the present invention. In the  
two-part pressure or locking plate, one part is adapted for mounting with  
respect to the screw member, and the other part is adapted for mounting to the  
45 femur, and is characterised in that the linear and/or angular relationship  
between the two parts may be adjusted as required, particularly in situ.

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### Summary of Invention

The present invention relates to a device for fixating a fractured femur, comprising :-

(a) an elongated screw member adapted for penetrating into at least the neck portion of a femur, comprising :-

a proximal portion comprising a first cylindrical member having an external first screw thread adapted for distal compressive engagement with bony tissue in particular within the femur;

a distal portion comprising a second cylindrical member having an internal cavity and a substantially open distal end, and at least one lateral portal for enabling communication between said cavity and an outside of said second cylindrical member;

an antimigration device accommodated in said cavity and comprising at least one anchoring means having gripping means, said at least one anchoring means being selectively extendable in a substantially lateral direction such that said gripping means extends to said outside of said distal portion via a corresponding one of said at least one portal, said gripping means being adapted for anchoring said antimigration device within bony tissue when said gripping means is brought into compressive engagement therewith;

and

(b) compression means releasably engageable with said distal portion of said screw member and selectively axially displaceable with respect thereto, said compression means having a proximal pressure face for selectively compressively engaging proximally with a distal end of said femur either directly or via any suitable washer interface such as a locking plate;

5 and is characterised in that said antimigration device comprises axially  
movable fixation means for selectively setting and fixing the relative axial  
10 position of said gripping means with respect to said second cylindrical  
member.

15 In the preferred embodiment, said first cylindrical member is integrally joined  
to said second cylindrical member, and said first screw thread comprises an  
external diameter substantially similar to an external diameter of said second  
20 cylindrical member. Further, said first cylindrical member comprises an axial  
lumen extending therethrough and having a proximal opening in said first  
cylindrical member and in communication with said cavity, said axial lumen  
and said cavity being of a size sufficient to enable a suitable alignment needle  
25 to be accommodated therein. Preferably, at least the proximal end of said first  
screw thread is self-taping with respect to bony tissue, and optionally said at  
least proximal end of said screw thread comprises a plurality of  
30 circumferentially spaced radial slots to provide portions of said screw thread in  
the form of blade-like elements separated by said radial slots, said blade like  
elements having leading edges adapted for taping into bony tissue.

35 In the preferred embodiment, said first screw thread comprises at least distal  
thread surfaces adapted for compressive engagement with bony tissue in  
40 response to a distal longitudinal force applied to said screw member. The said  
distal thread surfaces of said first screw thread preferably comprise a distal tilt  
angle of between about 2° to about 4°, and said first screw thread further  
45 comprises proximal thread surfaces having a proximal tilt angle of between  
about 30° to about 35°.

50 Optionally, said proximal portion of said screw member comprises at least one  
longitudinal groove for facilitating transportation of bony tissue debris from the  
55

5 proximal end to the distal end of said first cylindrical member during  
implantation of said device.

10 In the preferred embodiment, said at least one portal is in the form of a  
longitudinal slit along the cylindrical wall of said second cylindrical member,  
and said antimigration device comprises a proximally disposed ring,  
15 substantially coaxial with said second cylindrical member, and wherein said at  
least one anchoring means is in the form of a corresponding resilient arm  
cantilevered from said ring and extending substantially distally therefrom, said  
20 arm having a corresponding said at least one gripping means at the free distal  
end thereof, said antimigration device further comprising actuation means for  
reversibly extending said gripping means in a lateral direction . The actuation  
25 means may comprise an axially movable thrust element having an external  
second screw thread complementary to and engaged with an internal third  
screw thread comprised at least in a distal portion of said cavity of said second  
30 cylindrical member, wherein a proximal end of said thrust element comprises a  
convex conical surface, said conical surface adapted to abut against and urge  
said free end of said at least one arm laterally outwards in response to an axial  
35 translation in the proximal direction by said thrust element. The thrust element  
may comprise a substantially diametrical slot on the distal end thereof for  
engaging with an external complementary first tool so as to enable said thrust  
40 member to be axially displaced within said cavity by means of corresponding  
rotation of said first tool. The gripping means may comprise an externally  
facing tab having at least one bone-engaging edge, preferably said  
45 bone-engaging edge being serrated. In the preferred embodiment, said at least  
one arm is biased such that said tab does not significantly protrude from said  
corresponding at least one portal when said actuation means is disengaged  
50 from said anchoring means.



5 The axially movable fixation means for selectively setting and fixing the  
relative axial position of said gripping means with respect to said second  
10 cylindrical member may comprise a stub member engaged with and axially  
movable with respect to said ring member, said stub member having a proximal  
end for rotatably abutting against a proximal end of said cavity, and a distal  
15 end axially spaced from said engagement means. The stub member may  
comprise an external fourth screw thread complementary to and engaged with  
an internal fifth screw thread comprised in said second ring member, and the  
20 distal end of said stub member may also comprise a substantially diametrical  
slot for engaging with an external complementary second tool so as to enable  
said ring member to be axially displaced respect to said stub member by means  
25 of corresponding rotation of said second tool.

In the preferred embodiment, the said compression means comprises an axially  
movable first nut element having an internal sixth screw thread complementary  
30 to and engaged with an external seventh screw thread comprised at least in a  
distal portion of said second cylindrical member, and a proximal end of said  
first nut element preferably comprises a rounded annular edge.  
35 Advantageously, said first nut element comprises a pair of substantially  
diametrically opposed recesses on the distal end thereof for engaging with an  
external complementary third tool so as to enable said first nut element to be  
40 axially displaced within with respect to said screw member by means of  
corresponding rotation of said third tool.

45 In the first embodiment of the device the second cylindrical member comprises  
a pair of substantially diametrically opposed radial slots on the distal end  
thereof for engaging with an external complementary fourth tool so as to enable  
50 said screw member to be axially advanced into a femur by means of  
corresponding rotation of said fourth tool.

5 The preferred embodiment of the device optionally further comprises an axially  
engageable longitudinal extension member for effectively increasing the axial  
length of said screw member, wherein at least a proximal portion of said  
10 extension member comprises an external second screw thread complementary  
to and engaged with an internal third screw thread comprised at least in a distal  
portion of said cavity of said second cylindrical member, and wherein said  
15 compression means is releasably engageable with a distal portion of said  
extension member and selectively axially displaceable with respect thereto.  
Said extension member may be a tubular member having an external diameter  
substantially complementary to the internal diameter of said distal end of said  
20 screw member, and the said compression means comprises an axially movable  
second nut element having an internal eighth screw thread complementary to  
and engaged with said external second screw thread comprised in a distal  
portion of said extension member, the proximal end of said second nut element  
preferably comprising a rounded annular edge. Further, said second nut  
30 element advantageously comprises a pair of substantially diametrically  
opposed recesses on the distal end thereof for engaging with an external  
complementary fifth tool so as to enable said second nut element to be axially  
displaced within with respect to said extension member by means of  
35 corresponding rotation of said fifth tool. Also, such an extension member  
preferably comprises a pair of substantially diametrically opposed radial slots  
on the distal end thereof for engaging with an external complementary sixth  
tool so as to enable said extension member to be axially displaced with respect  
40 to said screw member by means of corresponding rotation of said sixth tool.

Alternatively, said extension member may be a stepped tubular member having  
50 a proximal portion and a distal portion, wherein said proximal portion of said  
tubular member comprises an external diameter substantially complementary to

5 the internal diameter of said distal end of said screw member, and wherein said  
distal portion of said tubular member comprises an external diameter  
10 substantially equal to the external diameter of said distal end of said screw  
member. With such an extension member, the compression means comprises  
an axially movable first nut element having an internal sixth screw thread  
15 complementary to and engaged with an external seventh screw thread  
comprised in at least a distal portion of said extension member, the proximal  
end of said second nut element preferably comprising a rounded annular edge.  
20 Further, said first nut element may comprise a pair of substantially  
diametrically opposed recesses on the distal end thereof for engaging with an  
external complementary third tool so as to enable said first nut element to be  
25 axially displaced within with respect to said extension member by means of  
corresponding rotation of said third tool. Also, the extension member may  
comprise a pair of substantially diametrically opposed radial slots on the distal  
30 end thereof for engaging with an external complementary fourth tool so as to  
enable said extension member to be axially displaced with respect to said  
screw member by means of corresponding rotation of said fourth tool.

35 The present invention also relates to a pressure plate for securing a femur nail  
or screw to a femur, used in fixating a fractured femur. While being novel per  
se, the pressure plate of the present invention is particularly useful in  
40 conjunction with the fixating device of the present invention. The pressure  
plate of the present invention is characterised in having an upper plate portion,  
a lower plate portion and adjusting means for adjusting at least one of the  
45 relative angular disposition and the relative linear displacement between said  
upper plate portion and said lower plate portion, and wherein said upper plate  
portion is adapted for rigid securement to said screw member (or to any  
50 suitable femur screw or nail) via said compression means, and wherein said

55

5 lower plate portion is adapted for rigid securement with respect to a distal  
portion of the femur. The lower plate portion preferably comprises a proximal  
10 surface having a profile complementary to a lower portion of said distal portion  
of the femur, and may be rigidly secured to said distal portion of said femur by  
at least one suitable screw via a corresponding at least one aperture comprised  
15 in said lower plate portion. The upper plate portion preferably comprises a  
proximal surface having a profile complementary to an upper portion of said  
distal portion of the femur, and comprises a first aperture adapted for  
20 securely engaging with a distal end of said device, and wherein said  
compression means compressively engages proximally with a distal end of said  
femur via said upper plate portion. When used with other femur screws or nails  
25 instead of the device of the present invention, the said upper plate portion is  
adapted for securement to the distal end of the femur screw or nail in a similar  
manner, mutatis mutandis. The pressure plate further comprises fixing means  
30 for fixing at least one of the relative angular disposition and the relative linear  
displacement between said upper plate portion and said lower plate portion.

35 When said compression means for the device is in the form of a nut member  
having a rounded proximal annular edge, said first aperture may have a flared  
distal entry complementary shaped to said rounded proximal annular edge.

40 In a first embodiment of the pressure plate, the adjustment means comprises a  
hinge arrangement having a first hinge element comprised at an upper end of  
said lower plate portion and a cooperating second hinge element comprised in  
45 said upper plate portion intermediate an upper end and lower end of said upper  
plate portion, said upper end of said upper plate portion comprising said first  
aperture and said lower end of said upper plate portion comprising said fixing  
50 means. In this embodiment, the fixing means comprises a at least one screw  
device having a first threaded portion engaged with and adapted for axial

5 displacement with respect to a complementary threaded second aperture  
comprised in said lower end of said upper plate portion, said threaded portion  
10 having a proximal end rotatably engaged with said lower plate portion, and  
wherein said at least one screw device further comprises an actuating portion  
so as to enable said at least one screw device to be axially displaced with  
15 respect to said upper plate portion by suitable means.

In a second embodiment of the pressure plate, the adjustment means comprises  
a linearly adjustable hinge arrangement having a first male hinge element  
20 comprised at an upper end of said lower plate portion and a cooperating  
second female hinge element comprised in said upper plate portion  
intermediate an upper end and lower end of said upper plate portion, said  
25 upper end of said upper plate portion comprising said first aperture and said  
lower end of said upper plate portion comprising said fixing means, wherein  
said female hinge element comprises a plurality of lateral apertures for  
30 selectively articulately engaging said male element in one of a corresponding  
plurality of relative linear relationships with respect to said lower plate portion  
via an articulating pin. In this embodiment, the fixing means comprises a at  
35 least one screw device having a first threaded portion engaged with and  
adapted for axial displacement with respect to a complementary threaded  
second aperture comprised in said lower end of said upper plate portion, said  
40 threaded portion having a proximal end for abutting against a distal surface of  
said lower plate portion, and wherein said at least one screw device further  
comprises an actuating portion so as to enable said at least one screw device to  
45 be axially displaced with respect to said upper plate portion by suitable means.

In a third embodiment of the pressure plate, the adjustment means comprises a  
50 linearly adjustable hinge arrangement having a first male hinge element  
comprised at an upper end of said lower plate portion and a cooperating

5 second female hinge element comprised in said upper plate portion  
intermediate an upper end and lower end of said upper plate portion, wherein  
10 said female hinge element comprises a plurality of lateral apertures for  
selectively articulately engaging said male element in one of a corresponding  
plurality of relative linear relationships with respect to said lower plate portion  
15 via an articulating pin, wherein said upper end of said upper plate portion  
comprises at least one said first aperture, and wherein said lower end of said  
upper plate portion comprises at least one said second aperture, said fixing  
20 means being associated with any one of said at least one second aperture. In  
this embodiment, the upper plate portion may be selectively engaged with  
respect to the said lower plate portion in one of a first or a second orientation  
25 corresponding to having said upper end or said lower end respectively, of said  
upper plate portion uppermost, wherein said at least one second apertures are  
substantially identical to said at least one first apertures, and wherein in said  
30 second orientation, one said second aperture is associated with said device and  
one said first aperture is associated with said fixing means. Further in this  
embodiment, the fixing means comprises a at least one screw device having a  
35 first threaded portion engaged with and adapted for axial displacement with  
respect to complementary threaded said second aperture comprised in said  
lower end or in said upper end of said upper plate portion, when said upper  
40 plate element is in said first or said second orientation, respectively, said  
threaded portion having a proximal end for abutting against a distal surface of  
said lower plate portion, and wherein said at least one screw device further  
45 comprises an actuating portion so as to enable said at least one screw device to  
be axially displaced with respect to said upper plate portion by suitable means.  
Preferably, said upper plate portion has a substantially S-shaped transverse  
50 cross-section.

5 In a fourth embodiment of the pressure plate, the adjustment means is in the  
form of a curved lower end comprised in said upper plate portion, said slot  
10 having laterally disposed shoulders parallel thereto and cooperating with a  
male reaction block comprised an upper end of said lower plate portion,  
wherein said curved lower end and said block comprising suitable profiles such  
15 as to enable the area of contact between said lower end and said block to be  
adjusted such as to provide at least one of a range of relative angular  
dispositions and a range of relative linear displacements between said upper  
20 plate portion and said lower plate portion. In this embodiment, the fixing  
means comprises at least one screw device for clamping said upper plate  
portion to said lower plate portion, said at least one screw device having a first  
25 threaded portion engaged with and adapted for axial displacement with respect  
to a complementary threaded third aperture comprised in said block of said  
lower plate portion, and wherein said at least one screw device further  
30 comprises a thrust surface for clamping contact with a distal surface of said  
lower portion, and an actuating portion so as to enable said at least one screw  
device to be axially displaced with respect to said lower plate portion by  
35 suitable means. The fixing means preferably comprises two said screw devices  
disposed along the length of said block, and the slot preferably has an open  
lower end.

40 The present invention also relates to methods for fixating a fractured femur,  
using the device of the present invention, optionally with one or more  
extension members.

45 The present invention also relates to methods for fixating a fractured femur  
using the pressure plate of the present invention together with the device of the  
50 present invention, or alternatively with any other suitable femur screw or nail  
device.

### Description of Figures

Figure 1 shows in side elevational cross-sectional view, the general anatomical areas of interest of a human femur.

Figure 2 shows a preferred embodiment of the present invention:-Figure 2(a):- in side elevational partial cross-sectional view; Figure 2(b):- a variation of proximal end of the embodiment in side elevational partial cross-sectional view; Figure 2(c):- the embodiment of Figure 2(b) viewed along Q-Q; Figure 2(d):- the pressure plate of Figure 2(a) in perspective view; Figure 2(e):- a transverse perspective view of Figure 2(d) along A-A; Figure 2(f):- a transverse perspective view of Figure 2(d) along B-B.

Figure 3 shows in side elevational cross-sectional view one embodiment of an extension member.

Figure 4 shows in side elevational partial cross-sectional view, the embodiment of Figure 2 having a modified tip and comprising the extension member of Figure 3.

Figure 5 shows in side elevational cross-sectional view detail (II) of screw thread portion of the embodiment of Figure 4.

Figure 6 shows in side elevational partial cross-sectional view, the distal part of the embodiment of Figure 2 having a comprising an alternative extension member.

Figure 7 shows in perspective view a first embodiment of the locking plate according to the present invention.

Figure 8 shows in plan view the embodiment of Figure 7.



5 Figure 9 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 8 taken along C-C.

10 Figure 10 shows in perspective view the lower plate portion of the embodiment of Figure 7.

15 Figure 11 shows in cross-section the embodiment of Figure 8 taken along D-D.

Figure 12 shows in cross-section the embodiment of Figure 9 taken along E-E.

20 Figure 13 shows in perspective view a second embodiment of the locking plate according to the present invention.

25 Figure 14 shows in plan view the embodiment of Figure 13.

Figure 15 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 14 taken along F-F.

30 Figure 16 shows in perspective view the lower plate portion of the embodiment of Figure 13.

35 Figure 17 shows in cross-section the embodiment of Figure 14 taken along G-G.

40 Figure 18 shows in cross-section the embodiment of Figure 15 taken along H-H.

45 Figure 19 shows in perspective view a third embodiment of the locking plate according to the present invention.

Figure 20 shows in plan view the embodiment of Figure 19.

50 Figure 21 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 20 taken along J-J.

55

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Figure 22 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 20.

10

Figure 23 shows in cross-section the embodiment of Figure 20 taken along K-K.

15

Figure 24 shows in cross-section the embodiment of Figure 20 taken along L-L.

20

Figure 25 shows in perspective view a fourth embodiment of the locking plate according to the present invention.

25

Figure 26 shows a rear view of the upper plate portion of the embodiment of Figure 25 in the direction (III).

30

Figure 27 shows in plan view the embodiment of Figure 25.

Figure 28 shows in side elevational cross-sectional view the upper plate portion of the embodiment of Figure 27 taken along M-M.

35

Figure 29 shows in perspective view the lower plate portion of the embodiment of Figure 25.

40

Figure 30 shows in cross-section the embodiment of Figure 27 taken along N-N.

45

Figure 31 shows in cross-section the embodiment of Figure 27 taken along O-O.

50

Figure 32 shows in side elevational partial cross-sectional view a first drill used for boring into the femur.

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5                   Figure 33 shows in side elevational partial cross-sectional view a second drill  
used for boring into the femur.

10                  Figure 34 shows in side elevational view a third drill used for boring into the  
femur.

15                  Figure 35 shows in side elevational partial cross-sectional view a screw holder  
engaged with the embodiment of Figure 2(a) having a lumen.

20                  Figure 36 shows in side elevational partial cross-sectional view a proximal  
portion of the screw holder of Figure 35.

25                  Figure 37 shows in side elevational partial cross-sectional view a special screw  
wrench engaged with the embodiment of Figure 2(a) having a lumen.

30                  Figure 38 shows in cross-sectional view the embodiment of Figure 37 taken  
along C-C.

35                  Figure 39 shows in side elevational partial cross-sectional view a proximal  
portion of the special screw wrench of Figure 37.

40                  Figure 40 shows in side elevational partial cross-sectional view a nut holder  
engaged with the embodiment of Figure 2(a) having a lumen.

45                  Figure 41 shows in side elevational partial cross-sectional view a proximal  
portion of the nut holder of Figure 40.

50                  Figure 42 shows in side elevational partial cross-sectional view an all-purpose  
wrench.

55                  Figure 43 shows in side elevational view an additional element for use in  
conjunction with the all-purpose wrench of Figure 42.

5

Figure 44 illustrates schematically the lumens required to be bored into the femur for implantation of the embodiments of Figures 1 to 6.

10

Figure 45 illustrates schematically a part of the implantation procedure for the embodiments of Figures 1 to 6 using the screw holder of Figures 35 and 36.

15

Figure 46 illustrates schematically a part of the implantation procedure for the embodiments of Figures 1 to 6 using the special screw wrench of Figures 37 to 39.

20

Figure 47 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur.

25

Figure 48 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur together with the pressure plate embodiment of Figures 7 to 12.

30

Figure 49 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur together with the pressure plate embodiment of Figures 13 to 18.

35

Figure 50 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur together with the pressure plate embodiment of Figures 19 to 24.

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Figure 51 illustrates schematically the embodiments of Figures 1 to 6 implanted in the femur together with the pressure plate embodiment of Figures 25 to 31

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### Disclosure of Invention

The present invention is defined by the claims, the contents of which are to be read as included within the disclosure of the specification, and will now be described by way of example with reference to the accompanying Figures.

In the present specification, the term "distal" (D) refers to a direction away from the trunk or body of the patient, while the term "proximal" (P) refers to a direction towards the trunk or body of the patient. Thus, referring to Figure 1, the femur head (2) is proximal with respect to the trochanter major (4).

The present invention relates to a device for fixating a fractured femur, in particular for holding in compression parts of a fractured femur neck. Referring to the Figures, Figures 2(a), 2(b) and 2(c) illustrate a preferred embodiment of the present invention. The device, designated by the numeral (200), comprises a screw member (20) and a compression means (210) releasably engageable with a distal portion of the screw member (20), and an axially settable antimigration device (300).

The screw member (20) comprises a proximal portion comprising a first cylindrical member (220) having a screw thread (31) along its outer surface. The screw thread (31) is adapted for compressive engagement with bony tissue, particularly bony tissue within the femur, in response to a longitudinal force applied distally to the screw member (20), i.e., along the central longitudinal axis (230) thereof. Accordingly, and referring to Figure 5, the screw thread (31) advantageously has a buttress-like transverse cross-sectional profile, in which the distally-facing thread surfaces (44) are approximately perpendicular to the longitudinal axis (230), while the proximally facing thread surfaces (43) is at an acute angle to this axis (230). Preferably, the distal thread surfaces (44) comprise a distal tilt angle  $\beta$  of between about 2° to about 4°, and

5 the proximal thread surfaces (43) comprise a proximal tilt angle  $\alpha$  of between  
about 30° and about 35°, said tilt angles being measured from a radial line  
10 perpendicular to the axis (230). This type of profile for the screw thread (31)  
reduces resistance from the bony tissue when helically advancing the device  
(200) in the proximal direction, while at the same time maximising the axial  
15 thrust resistance in the distal direction. Such high distal resistance (achieved  
together with action of compression means (210)) is advantageous in  
promoting compressive union of the fractured parts of the bone. The screw  
20 thread (31), in particular the proximal end thereof, is preferably self-tapping,  
minimising trauma in the bone during the insertion procedure which is thereby  
simplified. Preferably, and referring in particular to Figures 2(b) and 2(c), the  
25 proximal end of the screw thread (31) comprises a plurality of - in these  
figures, three - radial slots (235), thereby forming the remaining portions of the  
screw thread (31) separated by the slots (235) into blade-like elements (240)  
30 having radial leading edges (245). Said leading edges (245) are particularly  
sharpened and are thus well suited to facilitate the self-tapping action of the  
screw thread (31) into the bony tissue. Typically, the ratio between the outer  
35 diameter and the inner diameter of the screw thread (31) is about 3:2. Further  
typically, the screw thread (31) is integral with the said first cylindrical  
member (220).

40 Optionally, at least a proximal portion, and preferably the whole length of the  
first cylindrical member (220) further comprises at least one or a plurality, and  
45 optimally two or three, longitudinal grooves (42). The grooves (42) provide  
channels for bone debris formed during the tapping operation of the screw  
member (220) into the bone to be removed from the immediate vicinity of the  
50 screw thread (31) and thereby prevent premature clogging and jamming of the

5 screw member (220), which could restrict advancement of the screw member (220) into the femur and/or cause deterioration of the fracture .

10 The said first cylindrical member (220) may be solid, having a conical tip (30), as illustrated in Figure 2(a). Alternatively, the first cylindrical member (220) may comprises an axial lumen (29) extending therethrough and having an  
15 opening (40) in a truncated tip (30'), as illustrated in Figure 4. This lumen (29) is of a diameter sufficient to enable a suitable alignment needle to be accommodated therein, as described hereinbelow.

20 The screw member (20) further comprises a distal portion comprising a second cylindrical member (260) having an internal cavity (35) and a substantially open distal end (250). The second cylindrical member (260) is of a larger  
25 external diameter than the first cylindrical member (220), being typically approximately equal to the outer diameter of the screw thread (31). This geometry enables the first cylindrical member (220) to be proximally advanced into a distal part of the femur that is bored to accommodate the second  
30 cylindrical member (260). Thus, the size of the screw thread (31) is on the one hand maximised, while on the other hand providing stability and close fit of the second cylindrical member (260) within the bore provided for it at the distal  
35 end of the femur. Typically, the said first cylindrical member (220) is integrally joined to the second cylindrical member (260). The said second cylindrical member (260) also comprises a pair of substantially diametrically opposed radial slots (21) on the distal end thereof for engaging with an external  
40 complementary tool. The slots (21) enable the screw member (20) to be axially advanced into the femur by means of engagement of this tool with the slots (21), and rotation of the tool, which causes the screw member (20) to rotate  
45 and for the screw thread (31) to engage and penetrate into the femur, as will be further described hereinbelow.

50

55

5 The cavity (35) is in communication with the lumen (29) when the latter is  
formed in said first cylindrical member, and the cavity (35) is of a size at least  
10 sufficient to enable said alignment needle to be accommodated therein.  
Typically, though, the cavity (35) is much wider, and comprises a proximal  
wall (255) at the proximal end thereof, which may be in the form of a concave  
15 cone typically having truncated or pointed apex, depending on whether or not  
the first cylindrical member comprises a lumen (29), respectively.

20 The second cylindrical member (260) further comprises at least one lateral  
portal for enabling communication between the cavity (35) and the outside of  
the second cylindrical member (260). Typically about three such portals are  
provided, advantageously in the form of longitudinal slots (39) in the  
25 cylindrical wall (38) of the said second cylindrical member (260).

30 The compression means (210) are releasably engageable with a distal portion  
of the screw member (20) and is selectively axially displaceable with respect  
thereto. Further, the compression means (210) comprises a proximal pressure  
35 face (215) for engaging compressively, directly or indirectly, with a distal end  
of the femur. Thus, when the screw member (20) is positioned in place within  
the femur, and the compression means (210) are axially advanced proximally  
40 along the distal end of the screw member (20), the pressure face (215) and the  
distal thread surfaces (44) of the screw thread (31) compressively bring  
together the fractured segments of the femur. Thus, a distal longitudinal force is  
45 applied to the screw member (20) by virtue of the reaction of bone tissue on  
the distal thread surfaces (44) when proximal axial displacement of the  
compression means (210) urges the screw member (20) in a distal direction.  
50



Referring to Figures 2(a) and 6, the compression means (210) is, in the embodiment of Figure 2(a), in the form of an axially movable first nut element (51) having an internal screw thread (27) complementary to an external screw thread (34) comprised in at least a distal portion of the second cylindrical member (260). Preferably, the proximal end of the first nut element (51) comprises a rounded annular edge (52), and optionally further comprises a pair of diametrically opposed recesses (53) adapted for engagement with a special tool. As will be described hereinbelow, this special tool enables the first nut element (51) to be axially displaced with respect to the screw member (20) by means of a corresponding rotation of the tool.

Antimigration device (300) is accommodated in said cavity (35) and comprises at least one anchoring means having gripping means (320) for anchoring the device (200) in the femur once it has been positioned in place. The anchoring means are selectively extendible in the lateral direction, as will be explained hereinbelow, from a neutral or datum position to an extended position. In the datum position, the gripping means are typically enclosed within an envelope defined by the external surface of the second cylindrical member (260), and in the extended position the gripping means are extended through corresponding said portals, or slots (39) until the gripping means are brought into compressive engagement, substantially laterally, with bony tissue in the femur. In the present invention, the antimigration device (300) represents an improvement over prior art devices, and is characterised in comprising axially movable fixation means (310) which enable a user to selectively set and fix the axial position of the gripping means (320) with respect to the second cylindrical member (260). Thus, once the screw member (20) is positioned and set in place within the femur, the fixation means (310) enables the user to choose precisely where the gripping means (320) should be situated axially with

5 respect to the screw member (20), enabling the best choice of anchoring site within the femur to be chosen for each individual patient. This versatility in  
10 choosing the location of the anchoring site tremendously widens the universal adaptability of the device (200), since the device (200) can be adapted for optimal effect with patients having different optimal anchoring sites.

15 Thus, referring to Figure 2(a), the antimigration device (300) according to the present invention comprises a proximally disposed ring member (50) substantially coaxial with the axis (230) of the screw member (20). The  
20 anchoring means are in the form of a plurality of resilient arms (47) cantilevered from the ring member (50) and extending distally therefrom, one arm (47) corresponding to and aligned with each said slot (39). Each said arm (47) comprises a gripping means (320) at the free distal end thereof, the  
25 gripping means (320) being typically in the form of lateral externally facing tabs (22) accommodated within said corresponding slots (39) when the antimigration device (300) is in the datum unextended position. The tabs (22) have a bone-engaging outer edge, which is preferably serrated for improving  
30 the traction properties of the gripping means (320) with respect to the bony tissue that it is anchored in.

40 The axially movable fixation means (310) comprises a cylindrical stub member (62) having an external screw thread complementary to an internal screw thread of said ring member (50). The stub member (62) also comprises a distal end having a substantially diametrical slot (63) for engaging with an external  
45 complementary special tool or appropriate screwdriver, for example, and a proximal end (32) for rotatably abutting against proximal end wall (255) of cavity (35). Thus, with said tabs (22) engaged in their corresponding slots (39), the stub (62) may be rotated via engagement of a tool with slot (63), while the  
50 stub (62) is pressed against end wall (255), enabling the ring member (50) to

5           translate axially, thereby changing the relative axial position between the gripping means (320) and the screw member (20).

10           The antimigration device (300) further comprises actuation means for reversibly extending the gripping means (320) in a lateral direction. Referring to Figure 2(a), the actuation means comprises an axially movable thrust  
15           element (64) accommodated in said cavity (35) and having an external screw thread (321) complementary to and engaged with an internal screw thread (322) comprised in at least a substantial distal portion of the second cylindrical  
20           member (260). A proximal end of the thrust element (64) comprises a convex conical surface (65) which abuts against the inner part of the free end of each arm (47), such that as the thrust element (64) is axially translated in the  
25           proximal direction, the diameter of the part of the conical surface (65) in contact with the arms (47) increases, urging the arms (47) laterally outwards. In other embodiments, the thrust element (64) may comprise a proximal  
30           arm-engaging leading end having any suitable profile, for example a body of revolution having a parabolic profile, in which at the proximal end of the travel range of the thrust element (64) more revolutions thereof are required than at  
35           the distal end to extend the arms (47), providing greater efficiency since the resistance of the bony tissue to the implantation of said tabs (22) generally increases with the depth of implantation. The thrust element (64) comprises a  
40           substantially diametrical slot (66) in the distal end thereof for engaging with an external complementary special tool, or a suitable screwdriver for example, so as to enable the thrust member (64) to be axially displaced within the cavity  
45           (35) thereby. The length of stub member (62) is such as to provide a substantial spacing between its distal end and the thrust member (64), such as to avoid contact between the stub member (62) and the thrust member (64) for their  
50           respective full ranges of axial travel. The said arms (47) while resilient are

5 biased such that the tabs (22) do not protrude from their corresponding slots  
(39) at the datum position of the antimigration device (300), i.e., when the  
10 thrust member (64) is disengaged from the arms (47).

15 In a further aspect of universality, and referring to Figures 3, 4 and 6, the  
device (200) further optionally comprises at least one extension member (24)  
which is axially engageable with respect to the distal end of said screw  
20 member (20). The extension member (24) effectively increases the axial length  
of the screw member (20), thereby enabling the basic screw member (20) to be  
used with patients having anatomically larger femurs than for other patients for  
25 whom the basic screw member (20) is appropriately sized, such a basic size  
being typically correlated to an average statistical value for patients. Of course,  
rather than just one, there may be several extension members (24) of different  
30 axial lengths, each of which may be in turn engaged with the screw member  
(20) to provide the precise total axial length required, and thus quickly and  
effectively match the needs of each individual patient. Alternatively or  
35 additionally, two or more extensions members (24) may be adapted for  
engaging one with another in series with the screw member (24) to enhance the  
universality and versatility of the device (200). These aspects of the present  
40 invention represent a significant economic advantage in that custom made  
screw members are not needed for patients having anatomically larger bones.  
The extension member (24) is typically essentially tubular, and at least a  
45 proximal portion thereof comprises an external screw thread (56) which is  
complementary to and engages with the internal screw thread (322) comprised  
in the distal portion of the cavity (35). When using an extension member (24),  
50 the said compression means (210) are releasably engaged with and selectively  
axially displaceable with respect to a distal portion of the extension member

55

5 (24), rather than with the second cylindrical member (260). Similarly, if more  
than one extension member (24) is engaged with the second cylindrical  
10 member (260) in series, the compression means (210) are typically engaged  
with the most distal extension member (24).

15 As illustrated in Figures 3 and 4, the extension member (24) may be a  
non-stepped tubular extension member (24") having a mean external diameter  
substantially similar to the mean internal diameter of the distal end of the screw  
20 member (20). In other words, the external diameter of the tubular extension  
member (24") is complementary to the internal diameter of the second  
cylindrical member (260), taking into account the corresponding screw threads  
(56) and (322), respectively. In this case, the compression means (210)  
25 comprises an axially movable second nut element (59), having an internal  
screw thread (256) which is complementary to and engages with the external  
screw thread (56) comprised in the distal portion of the tubular extension  
30 member (24"). Preferably, the proximal end of the second nut element (59)  
comprises a rounded annular edge. Advantageously, the second nut element  
(59) also comprises a pair of substantially diametrically opposed recesses (61)  
35 on the distal end thereof for engaging with a suitable external complementary  
tool. The recesses (61) enable the second nut element (61) to axially displaced  
with respect to the screw member (20) by means of the engagement and  
40 rotation of such a tool with the second nut element (59).

45 As with the second cylindrical member (260), the said tubular extension  
member (24") may optionally comprise a pair of substantially diametrically  
opposed radial slots (257) on the distal end thereof for engaging with an  
external complementary tool. Once the tubular extension member (24") is  
50 axially locked with respect to the screw member (20), the slots (257) enable  
the screw member (20) to be axially advanced into the femur by means of

5 engagement of this tool with the slots (257), and rotation of the tool, which  
causes the screw member (20) to rotate as a complete unit with the tubular  
10 extension member (24"), and for the screw thread (31) to engage and penetrate  
into the femur, as will be further described hereinbelow. An advantage of this  
tubular embodiment (24") of the extension member (24) is that it may be  
15 advanced into the said second cylindrical member (260) to any one of a range  
of depths, and therefore enables the total axial length of the device (200) to be  
finely tuned and thus matched to a particular patient having anatomical  
20 parameters within a predetermined range.

Alternatively, and as illustrated in Figure 6, the extension member (24) may be  
25 in the form of a stepped extension member (24') having a proximal portion  
(258) and a distal portion (54). The proximal portion (258) has an external  
diameter substantially complementary to the internal diameter of the distal end  
of the screw member (20), and comprises an external screw thread (56)  
30 complementary to and for engaging with internal screw thread (322) of the  
second cylindrical member (260). The distal portion (54) comprises a larger  
external diameter, substantially equal to that of the distal end of the screw  
35 member (20), and also comprises a similar external screw thread (57) to the  
external screw thread (34) on the distal end of the second cylindrical member  
(260). Thus, the compression means (210) that may be used in conjunction  
40 with this embodiment (24') of the extension member (24) may be the same nut  
element (51) that is used with the basic screw member (200), mutatis mutandis.  
45 When this embodiment (24') of the extension member (24) is used with the  
screw member (20), the stepped extension member (24') is screwed into the  
distal end of the second cylindrical member (260), typically until the  
50 proximally facing annular shoulder (259) between distal portion (54) and

5 proximal portion (258) of the stepped extension member (24') abuts the distal end of the second cylindrical member (260).

10 The stepped tubular member (24') may also optionally comprise a pair of substantially diametrically opposed radial slots (58) on the distal end thereof for engaging with an external complementary tool. Once this embodiment of  
15 the extension member (24') is axially locked with respect to the screw member (20), the slots (58) enable the screw member (20) to be axially advanced into the femur by means of engagement of this tool with the slots (58), and rotation  
20 of the tool, which causes the screw member (20) to rotate as a complete unit with the extension member (24'), and for the screw thread (31) to engage and penetrate into the femur, as will be further described hereinbelow. An  
25 advantage of this stepped tubular embodiment of the extension member (24') is that it may be used with the same compression means (210) that is used for the basic screw member (20), thereby reducing the number of different  
30 components that may be required by a user.

Optionally, said stepped extension member (24') may comprise an internal  
35 screw thread at least at the distal end thereof complementary to the external screw thread (56) of another stepped or non-stepped extension member, hereby another extension member to be mounted distally thereto, and thus increase the  
40 effective length of the screw member (20).

45 As illustrated schematically in Figures 2(a), 2(d), 2(e) and 2(f), the device (200) of the present invention may further optionally comprise a locking plate (400) for further securing the screw member (20) to the femur. The locking  
50 plate (400) is of particular use when fixating lateral neck fractures, and is mounted to the outer distal surface of the femur, typically close to the under  
55

5 trochanter area (6) of the bone. While unitary locking plates known in the art  
may be used in conjunction with said screw member (20), adapted accordingly,  
10 the locking plate (400) of the present invention is particularly characterised in  
comprising an upper plate portion (410) and a lower plate portion (420), and  
adjustment means (430) for adjusting the relative angular disposition and/or the  
15 relative linear displacement between the upper plate portion (410) and the  
lower plate portion (420). The upper plate portion (410) is adapted for rigid  
securement to the screw member, typically via the compression means (210),  
20 while the lower plate portion (420) is adapted for rigid securement to a distal  
part of the femur. As illustrated in Figures 2(e) the upper plate portion (410)  
advantageously comprises a proximal surface having a profile complementary  
25 to a upper portion of the distal part of the femur onto which the upper plate  
portion (410) abuts. Similarly, and as illustrated in Figures 2(f) the lower plate  
portion (420) advantageously comprises a proximal surface having a profile  
complementary to a lower portion of the distal part of the femur onto which the  
30 lower plate portion (420) abuts. As illustrated in Figure 2(d), the upper plate  
portion (410) comprises a first aperture (415) adapted for securely engaging  
with a distal end of the device (200), and said lower plate portion (420) may be  
rigidly secured to the distal portion of the femur by at least one, and preferably  
35 by as plurality of nails or wood screws, for example, via corresponding  
apertures (425) comprised in said lower plate portion (420). The relative  
angular disposition between the upper plate portion (410) and the lower plate  
portion (420) may be fixed at any desired value, typically according to the  
45 geometry of the individual femur and the fractures contained therein by fixing  
means (500)

50 Referring to Figures 7 to 12, a first embodiment (67) of the pressure plate  
(400) comprises an upper plate portion (69) having profiled proximal surface



5 (73), and a first aperture (70) adapted for engaging with the distal end of  
device (200). Thus, aperture (70) is of a size to allow the distal end of device  
10 (200) to be threaded therethrough, if the device (200) is used without any  
extension member (24), or alternatively for the distal end of the extension  
member (24) to protrude therefrom, according to whether the stepped tubular  
15 extension member (24') or tubular extension member (24'') is used with the  
device (200). Advantageously, the aperture (70) has a concave rounded edge  
(71) complementary to the rounded annular edge (52) or (60), according to  
20 whether nut element (51) or nut element (59), respectively, is used as the  
compression means (210). In this embodiment, the pressure plate (400) also  
comprises a lower plate portion (68) having profiled proximal surface (72) and  
25 a plurality of apertures (70) for enabling nails or wood screws to secure the  
lower plate portion (70) to the femur.

30 The adjustment means (430) comprises a mechanically detachable hinge  
arrangement (450) having a first hinge element (451) comprised at the upper  
end of said lower plate portion (68), and a cooperating second hinge element  
(452) comprised in said upper plate portion (69) intermediate between the  
35 upper end and the lower end thereof. Thus, rotation of the upper plate portion  
(69) with respect to the lower plate portion (68) via the hinge arrangement  
(450) enables the relative angular dispositions therebetween to be adjusted.

40 In the first embodiment (67) of the pressure plate (400), said fixing means  
(500) comprise at least one screw device (75) having a first threaded portion  
45 engaged with and adapted for axial displacement with respect to a  
complementary threaded second aperture comprised in said lower end of said  
upper plate portion (69). The said threaded portion comprises a proximal end  
50 engaged with and capable of rotating with respect to said lower plate portion.  
The said at least one screw device (75) further comprises an actuating portion

5 (501) for enabling the screw device (75) to be rotated. Thus, actuating portion  
10 (501) may be adapted for manually turning the same, or alternately may  
comprise means such as a diametrical slit or hexagonal pit, for example, for  
engaging with a suitable external tool so as to enable said screw device (75) to  
15 be axially displaced with respect to said upper plate portion (69) by means of  
corresponding rotation of said external tool.

20 Referring to Figures 13 to 18, a second embodiment (76) of the pressure plate  
(400) comprises an upper plate portion (78) having profiled proximal surface  
(82), and a first aperture (79) adapted for engaging with the distal end of  
25 device (200). Thus, aperture (79) is of a size to allow the distal end of device  
(200) to be threaded therethrough, if the device (200) is used without any  
extension (24), or alternatively for the distal end of the extension member (24)  
30 to protrude therefrom, according to whether the stepped extension member  
(24') or tubular extension member (24'') is used with the device (200).  
Advantageously, the aperture (79) has a concave rounded edge (80)  
35 complementary to the rounded annular edge (52) or (60), according to whether  
nut element (51) or nut element (59), respectively, is used as the compression  
means (210). In this embodiment, the pressure plate (400) also comprises a  
40 lower plate portion (77) having profiled proximal surface (81) and a plurality of  
apertures (503) for enabling nails or wood screws to secure the lower plate  
portion (77) to the femur.

45 In this embodiment, the adjustment means (430) comprises a mechanically  
detachable and linearly adjustable hinge arrangement having a first male hinge  
50 element (505) comprised at an upper end of said lower plate portion (77) and a  
cooperating second female hinge element (506) comprised in said upper plate

5 portion (78), intermediate an upper end and lower end of said upper plate  
portion (78). The female element (506) comprises a slot (85) for enabling the  
10 male element (505) to be engaged therein. The upper end of said upper plate  
portion (78) comprises said first aperture (79), and said lower end of said  
upper plate portion (78) comprising said fixing means (500). The said female  
15 hinge element comprises a plurality of lateral apertures (86) for selectively  
articulatingly engaging said male element (505) in one of a corresponding  
plurality of relative linear relationships with respect to said lower plate portion  
20 via an articulating pin. Thus, both the relative linear and angular dispositions of  
the upper plate portion (78) may be adjusted with respect to the lower plate  
portion (77) by respectively engaging the male element (505) with one of the  
25 linear positions corresponding to apertures (86), and by rotating about the  
hinge formed at that portion with the articulating pin.

30 In this embodiment, the fixing means (500) comprises a at least one screw  
device (84) having a first threaded portion engaged with and adapted for axial  
displacement with respect to a complementary threaded second aperture  
35 comprised in said lower end of said upper plate portion (78). The said threaded  
portion comprises a proximal end engaged with and capable of rotating with  
respect to said lower plate portion (77). The said at least one screw device (84)  
40 further comprises an actuating portion (508) for enabling the screw device (75)  
to be rotated. Thus, actuating portion (508) may be adapted for manually  
turning the same. Preferably, the actuating portion (508) may comprise means  
45 such as a diametrical slit, for example, for engaging with a suitable external  
tool so as to enable said screw device (84) to be axially displaced with respect  
to said upper plate portion (78) by means of corresponding rotation of said  
50 external tool.

5 Referring to Figures 19 to 24, a third embodiment (87) of the pressure plate  
(400) comprises an upper plate portion (89) having profiled proximal surface  
(93), and at least a first aperture (90) adapted for engaging with the distal end  
10 of device (200). Thus, aperture (90) is of a size to allow the distal end of  
device (200) to be threaded therethrough, if the device (200) is used without  
any extension (24), or alternatively for the distal end of the extension member  
15 (24) to protrude therefrom, according to whether the stepped extension  
member (24') or tubular extension member (24'') is used with the device (200).  
Advantageously, the aperture (90) has a concave rounded edge (91)  
20 complementary to the rounded annular edge (52) or (60), according to whether  
nut element (51) or nut element (59), respectively, is used as the compression  
means (210). In this embodiment, the pressure plate (400) also comprises a  
25 lower plate portion (88) having profiled proximal surface (92) and a plurality of  
apertures (509) for enabling nails or wood screws to secure the lower plate  
portion (88) to the femur.

30 In this embodiment, said adjustment means (430) comprises a linearly  
adjustable hinge arrangement having a first male hinge element in the form of  
35 two parallel distally extending plates (510) comprised at an upper end of said  
lower plate portion (88), and a cooperating second female hinge element (511)  
comprised in said upper plate portion (87) intermediate an upper end and lower  
40 end of said upper plate portion (87). The female hinge element (511) comprises  
a plurality of lateral apertures (95) for selectively articulately engaging said  
plates (510) in one of a corresponding plurality of relative linear relationships  
45 with respect to said lower plate portion (88) via an articulating pin.  
Furthermore, the upper end of said upper plate portion (87) comprises at least  
50 one and preferably two or more said first aperture (90), and said lower end of

5           said upper plate portion (87) comprises at least one and preferably two or more second apertures (90').

10           The said fixing means (500) is associated with said second aperture (90') comprised in said lower end of said upper plate portion (89). In this embodiment, the fixing means comprises at least one screw device (not  
15           shown) having a first threaded portion engaged with and adapted for axial displacement with respect to complementary threaded aperture comprised in said upper end of said lower plate portion (88). The threaded portion has a  
20           distal end that passes through the second aperture (90') comprised in said upper plate portion (89), and the screw device further comprises an actuating portion having means for engaging with a suitable external tool (or manually) so as to  
25           enable said at least one screw device to be axially displaced with respect to said lower plate portion (88). The screw device also has a thrust surface for moving the said upper plate portion (89) via the second aperture (90') as the  
30           screw device is moved with respect to the lower plate portion (88). In this embodiment, the relative linear disposition between the upper plate portion (89) and the lower plate portion (88) may be adjusted according to via which  
35           aperture (95) these portions are hinged, and the corresponding relative angular disposition adjusted by rotation about the hinge. Moreover, further linear adjustment of the whole pressure plate (87) is possible by virtue of the fact that  
40           the pressure plate (87) may be mounted to the device (200) via any one of the apertures (90) in the upper part of the upper plate portion (89), which apertures (90) are linearly spaced one from another. Furthermore, the upper plate portion  
45           (89) is preferably S-shaped in transverse profile and may be selectively engaged with respect to the said lower plate portion (88) in one of a first or a second orientation corresponding to having said upper end or said lower end  
50           respectively, of said upper plate portion (89) uppermost. In such a case, second

55

5 apertures (90') are substantially identical to said first apertures (90), and thus in  
the second orientation any one of apertures (90') is used for securing the  
10 pressure plate (87) to the device (200), while the first apertures (90) are  
associated with the fixing means (500). The upper end and lower ends of the  
upper plate portion (89) are of different linear lengths to increase the range of  
15 linear adjustments possible with this embodiment.

Referring to Figures 25 to 32, a fourth and preferred embodiment (96) of the  
pressure plate (400) comprises an upper plate portion (98) having profiled  
20 proximal surface (101), and a first aperture (99) adapted for engaging with the  
distal end of device (200). Thus, aperture (99) is of a size to allow the distal  
end of device (200) to be threaded therethrough, if the device (200) is used  
25 without any extension (24), or alternatively for the distal end of the extension  
member (24) to protrude therefrom, according to whether the stepped tubular  
extension member (24') or tubular extension member (24'') is used with the  
30 device (200). Advantageously, the aperture (99) has a concave rounded edge  
(100) complementary to the rounded annular edge (52) or (60), according to  
whether nut element (51) or nut element (59), respectively, is used as the  
35 compression means (210). In this embodiment, the pressure plate (400) also  
comprises a lower plate portion (97) having profiled proximal surface (102)  
and a plurality of apertures (105) for enabling nails or wood screws to secure  
40 the lower plate portion (97) to the femur.

In this embodiment, said adjustment means (430) is in the form of a curved  
45 lower end (530) comprised in said upper plate portion (98) and having a slot  
(103). The slot (103) comprises laterally disposed shoulders (525) parallel  
thereto and cooperating with a male reaction block (520) comprised an upper  
50 end of said lower plate portion (97). The said curved lower end (530) and said  
block (520) comprise suitable profiles such as to enable the area of contact

5 between said lower end (530) and said block (520) to be adjusted such as to  
provide at least one of a range of relative angular dispositions and a range of  
10 relative linear displacements between said upper plate portion (98) and said  
lower plate portion (97). Thus, the shoulders (525) may slide along the distal  
portion (526) of block (520) to adjust the relative linear dispositions of the  
15 upper plate portion (98) and the lower plate portion (97). Additionally or  
alternatively, the shoulders (525) may rotate over the distal portion (526) of  
block (520) to adjust the relative angular dispositions of the upper plate portion  
20 (98) and the lower plate portion (97).

In this embodiment, the fixing means (500) comprises at least one and  
preferably two screw devices (104) for clamping said upper plate portion (98)  
25 to said lower plate portion (97). Each screw device (104) comprises a first  
threaded portion engaged with and adapted for axial displacement with respect  
to a complementary threaded third aperture comprised in the distal portion  
30 (526) of said block (520) of said lower plate portion (97). Furthermore, each  
screw device (104) further comprises a thrust surface for clamping contact with  
a distal surface of said lower portion (530), and an actuating portion having  
35 means for engaging with a suitable external tool so as to enable said at least  
one screw device to be axially displaced with respect to said lower plate  
portion, particularly by means of corresponding rotation of said external tool.  
40

Preferably, said slot (103) has an open lower end, enabling the upper plate  
portion (98) to be attached or detached from the lower plate portion (97)  
45 without removing the screw devices (104).

50 While the pressure plate (400) of the present invention may be advantageously  
used in conjunction with said screw member (20) (optionally including  
55

5 extension member (24)) and compression means (210), the said pressure plate  
(400) is novel per se, and in fact may be used with any suitable femur screw or  
10 nail arrangement having a distal end, the upper plate portion (410) being  
adapted for rigid securement with respect to such a distal end of the femur  
screw or nail arrangement instead of the screw member (20) / compression  
15 means (210) of the present invention, mutatis mutandis.

20 The device (200) of the present invention is associated with a set of adjusting  
tools including: a first spiral drill for the bone, a second spiral drill for the  
bone; a third spiral drill; a screw holder for femur neck osteosynthesis; a  
25 special wrench for adjusting the screw for femur neck osteosynthesis together  
with the antimigration device; a special wrench for adjusting the hold-down  
and additional nut of the screw for femur neck osteosynthesis; an all-purpose  
wrench for femur neck osteosynthesis.  
30

Referring to Figure 32, the first spiral drill (106) for the bone has a central axis  
(107) and a coaxial lumen (108) sized to accommodate an alignment needle,  
35 and an outer diameter no less than the inner diameter of thread (31) of screw  
member (20). The length of the cutting spiral (109) is typically not less than the  
maximum femur neck length.  
40

Referring to Figure 33, the second spiral drill (110) for the bone also has a  
central axis (111) and a coaxial lumen for accommodating the alignment  
45 needle. The outer diameter of the second drill is greater than the inner diameter  
of thread (31) and serves to drill tolerance in bone material. The length of  
cutting spiral (113) is typically not less than the maximum femur neck length.  
50

Referring to Figure 34, the third spiral drill (114) for the bone has an outer  
55



5 diameter greater than the outer diameter of the second cylindrical member  
(260), and the length of the cutting spiral is typically not less than the length of  
10 the second cylindrical member (260).

Referring to Figures 35 and 36, screw holder (116) for femur neck  
osteosynthesis comprises a body (117) having a handle (118) at a distal end  
15 thereof, and an axial well (119) on the proximal end thereof. The well (119)  
comprises an internal screw thread (550) complementary to the external screw  
thread (34) of screw member (20). Holder (116) further comprises a lumen  
20 (120) coaxial with a central axis thereof and extending through said body (117)  
and handle (118), the lumen (120) being sized to accommodate said alignment  
needle. Holder (116) is used for imparting rotary movement to screw member  
25 (20) and thus enabling the screw member (20) to be driven into the proximal  
part of femur neck. Screw member (20) is implanted into the proximal part of  
femur neck without extension sleeve, when this is also needed, the extension  
30 sleeve being subsequently engaged with screw member (20) separately, after  
removing holder (116).

Referring to Figures 37 to 39, a special wrench (121) may be used for  
35 adjusting the screw member (20) for femur neck osteosynthesis together with  
antimigration device (300). Such a wrench is disclosed in SU 1715335, the  
contents of which are included herein in their entirety by reference thereto.  
40 Wrench (121) comprises a body portion (122) having a handle (123) at a distal  
end thereof, and further comprising a well (124) on the proximal end of the  
body portion (122). At least a proximal portion of the external surface (125) of  
45 body portion (122) comprises an external screw thread (126), and two  
diametrically opposed longitudinal slots (127) are formed in the body within  
the externally threaded portion of the body portion (122). A reciprocable  
50 spring-loaded actuator in the form of a tab (128) has its lateral ends extending

5 through said longitudinal slots, enabling the tab to slide axially between the  
ends of the slots (127). The lateral ends of the tab (128) are enclosed within a  
10 hollow nut member (129) having an internal screw thread complementary to  
and engaged with said external screw thread (126), enabling the nut member  
(129) to be axially translated over the body member (122), taking said tab  
15 (128) therewith. Tab (128) is biased in the proximal direction by means of a  
pushing element (130) coupled to a spring (131) comprised in the body portion  
(122). This wrench (121) is typically applied when the bone material offers a  
20 considerable resistance to the implantation of screw member (20), wherein  
considerable effort is required to drive it in and then to separate wrench (121)  
from screw member (20). Furthermore, wrench (121) is also particularly useful  
25 for removing screw member (20) from the femur once the osteosynthesis  
process has been completed and complete union of femur neck chips has  
occurred (according to medical indications or the patient's desire).

30 Referring to Figures 40 and 41, a special wrench (132) is provided for  
adjusting nut members (51) or (59). The wrench (132) comprises a body (133)  
having a turning handle (134) disposed at a distal end thereof. The proximal  
35 end of the body (133) comprises a well (135) adapted for receiving a distal end  
of second cylindrical member (260) (or the distal end of extension member  
(24), and has an internal diameter greater than the external diameter thereof  
40 including a radial clearance therebetween. A pair of diametrically opposed pins  
(136) are arranged on the annular distal face (555) of the body (133). The pins  
(136) are adapted for registration and engagement with recesses (53) or (61)  
45 comprised in nut members (51) and (59), respectively.

50 Referring to Figures 42 and 43, the set of adjusting tools further includes  
all-purpose wrench (137) comprising an elongate body (138) having a  
detachable handle intermediate the axial ends thereof. On one end of body  
55

(138) are comprised means for imparting rotary motion to screw member (20) or to extension sleeve (54), and such means include a step-shaped ribbed pin (140) having diametrically opposed axial ribs (141) which are adapted for registration and engagement with slits (21) or (58), respectively. On the other axial end of body (138) a well (142) is provided with a pair of diametrically opposed axially projecting flanges (143). Said flanges are adapted for registering and engaging with complementary recesses (145) comprised at one end of an elongate element (144). The other end of elongate element (144) comprises a tab (146) adapted to engage lateral slot (63) or (66) of said stub (62) or thrust member (64), respectively. All-purpose wrench (137) is typically used after screw member (20) has been fully driven into the bone, and it is necessary to deepen it proximally a little further to mount the extension sleeve. Furthermore, the wrench (137) is also particularly useful for mounting the extension sleeve, as well as (in combination with additional element (144) for adjusting the location of the antimigration device (300) with respect to stub (62), or for actuating the antimigration device (300) by means of thrust member (64).

The device (200) of the present invention may be used as follows..

Fracture fragments are reponed under periodic X-ray observation. A 3-4 cm long cut is made to expose undertrochanter area (6) of the femur. In the spot wherein Trochanter major changes to Diafiz (8) an alignment needle is passed, by means of a drill, in direction of the femur neck axis (19). The bone cortical layer (7), approximately 2 cm thick, around the distal end of the needle, is removed typically with a chisel. Then, under periodic X-ray monitoring, a stepped bore is drilled out in the femur using in succession first spiral drill

(106), second spiral drill (110) and third spiral drill (114), as illustrated in Figure 44. The first spiral drill (106) and second spiral drill (110) are aligned by means of lumens (108), (112) respectively and the alignment needle, and each drill is in turn advanced proximally along the femur neck axis (19) using the alignment needle as a guide rod. The drilling depth for each of the first drill (106) and for the second drill (110) is a little greater than the length of screw member (20). Particularly in the case of elderly patients, sometimes only the first drill (106) is needed, since introduction of the screw member (20) does not pose too great a resistance given the close tolerance between the first cylindrical member (220) and the bore created by the first drill (106). However, with younger patients, the resistance is generally greater and therefore greater dimensional tolerance is required, and this is accomplished by drilling a wider bore with second drill (110), in addition to or instead of the original bore drilled out by the first drill (106). The third spiral drill (114) is typically advanced by a brace to the depth of this part of the bore which exceeds a little the length of second cylindrical member (260), thereby expanding radially the distal part of the bore drilled by the first drill (106) and second drill (110). In cases where the third drill also comprises an axial lumen, the alignment needle may be used instead of the brace for aligning the third drill.

Referring to Figure 45, the screw member (20) is driven into the femur along axis (19) by rotating same about its axis (230) using holder (116), wherein the distal end of screw member (20) is engaged in well (119) thereof, and relative axial movement between member (20) and the holder (116) is prevented by nut member (51). The screw member (20) is advanced proximally into the full length of the wider part of the bore drilled by the third drill (114), and then driven into the remaining proximal part of this bore using the elf-taping screw

5 thread (31).

10 Bone chips generated in the self-tapping process fill grooves (42) comprised in the mid-section of the first cylindrical body. Referring to Figure 4, the lumen (29) may be used in conjunction with the alignment needle as a guide rod to align the screw member (20) more precisely. To this end the alignment needle is  
15 passed in through lumen (29) and cavity (35) of the screw member (20) (the antimigration device (300) having been removed previously), and in through the lumen (120) of holder (116). Once screw member (20) has been driven into the femur, the holder (116) is separated from screw member (116), for example  
20 by first advancing the nut member (51) in a proximal direction and then rotating the holder (116) so that it translates in a distal direction. Then, the antimigration device (300) is mounted into the cavity (35) via the distal end of the screw member (20). Such a procedure of setting screw member (20) is used  
25 when the severity of bone osteoporosis is very high.

30  
35 Preferably, and referring to Figure 46, the screw member (20) is implanted together with the antimigration device (300). Advantageously, special wrench (121) may be used for this purpose, wherein screw member (20) is initially  
40 engaged by its external screw thread (34) with the threaded well (124) up to abutment with nut member (51). Then, tab (128) is advanced proximally via hollow nut (129) until it engages with slits (21), and then the screw member (20) is driven proximally by turning handle (123) of the special wrench (121)  
45 This is carried out in a similar manner as with holder (116). Once screw member (20) has been implanted to the required depth, the special wrench (121) is separated therefrom. To facilitate this uncoupling hollow nut (129) is  
50 rotated to advance slightly in a proximal direction, wherein tab (128) is slightly

5 advanced along slits (127) and acting axially on slits (21).

10 Once screw member (20) has been fully implanted, femur head (2) and neck (3) are brought together and held down in compression. To this end special wrench (132) is used to turn nut member (51) via pins (136) and recesses (53), until nut member (51) is pressed against the bone cortical surface (7).  
15 Tightening the nut member (51) further provides a distal force to the screw thread (31) and a reaction force to the pressure face (215), causing compression of the bone endosteum. The femur head (2) and neck (3) are thus  
20 made coincident and pressed together tightly.

25 If the length of screw member (20) is inadequate, it can be increased by using one or several extension sleeves (24), for example. The extension member (24) is partly screwed in along thread (36) into internal axial cavity (35) by means of all-purpose wrench (137). If the tubular extension member (24") is used,  
30 then to hold together femur head (2) and neck (3), second nut element (59) may be used, and this may also be screwed in place using special wrench (137). Of course, if the stepped extension member (24') is used, then the first  
35 nut element (51) can be used as with the basic screw member (20).

40 Referring to Figure 47, when the bone parts are brought together in compression, antimigration device (300) is positioned in the desired place and fixed. To position antimigration device (300) in the desired place threaded stub  
45 (62) is turned by means of additional element (144) of all-purpose wrench (137), for example, causing ring member (50) to advance axially within cavity (35) (under periodic X-ray monitoring) until the ends of its arms (47) come into  
50 the necessary position inside the bone, near cortical layer (7). Then the arms (47) drawn aside and extended from slots (39) by means of thrust member (64)

5 as this is advanced proximally by means of the additional element (144), for  
example. The tabs (48) are then driven into the bone and the antimigration  
10 device (300) is fixed in the desired position and a paddle-like anchoring system  
is formed to hold screw member (20) inside the bone and minimise mobility  
and rotation of bone fragments.

15  
Particularly for use in treating lateral undertrochanter, intertrochanter and  
20 transtrochanter fractures of femur neck, pressure plate (400) may be mounted  
onto the femur external surface near undertrochanter area (6), using the  
following generalised procedure. Screw member (20) is mounted to the femur  
25 as described above, and bone parts are brought into coincidence compressively  
by tightening nut member (51) (or nut member (59) if the tubular extension  
member (24") is also used), antimigration device (300) is set in necessary  
30 position and fixed. Next, the nut member (51) is unscrewed, pressure plate  
(400) is mounted onto screw member (20), and then nut member (51)  
re-screwed onto screw member (20) to rigidly hold in place pressure plate  
35 (400) with respect to the screw member (20). A similar procedure is used with  
nut member (59), mutatis mutandis. In these cases, the pressure plate (400)  
also acts as a washer between the nut member and the bone. If the pressure  
40 plate is a unitary plate, it is then fixed to the femur in the usual manner. When  
using the pressure plate according to the present invention, fixing of the  
pressure plate (400) to the femur is effected when the desired angular and/or  
45 linear dispositions between the upper plate portion (410) and the lower plate  
portion (420) is adjusted and fixed, as will be described below in the context of  
several embodiments of said pressure plate (400).

50 Referring to the first embodiment of the pressure plate (67) illustrated in

5 Figures 7 to 12, and to Figure 48, the upper plate portion (69) is rigidly  
attached to the distal end of screw member (20) via aperture (70) and by  
10 screwing nut member (51) or nut member (59) to screw member (20). Then,  
the lower plate portion (68) is mounted to the upper plate portion (69) via the  
hinge arrangement (450). To suit patients with different anthropometric  
15 dimensions of femur neck, both parts of pressure plate (67), the upper plate  
portion (69) and the lower plate portion (68) are matched within a certain range  
of angular and/or spatial positions by detachable articulated hinge arrangement  
20 (450), and this is performed until pressure plate (67) tightly fits to femur  
undertrochanter area (6). Then, the upper plate portion (69) and the lower plate  
portion (68) are rigidly fixed together in this position by screw device (75).  
25 Then lower plate portion (68) is rigidly mounted, by means of nails and/or  
wood screws to the external surface of femur undertrochanter area (6) via  
apertures (74), which are preferably in staggered arrangement as illustrated in  
30 Figure 10 to provide more reliable attachment of pressure plate (67) to femur  
undertrochanter area (6). Proximal surfaces, (72) and (73) of the pressure plate  
(67) have profiles complementary in relation to the adjacent external surface of  
35 femur undertrochanter area (6) to provide better fit therebetween.

Referring to Figures 13 to 18 and 49, the second embodiment of the pressure  
40 plate (76) is mounted in a similar manner as for the said first embodiment (67),  
*mutatis mutandis*.

Thus, the upper plate portion (78) is rigidly attached to the distal end of screw  
45 member (20) via aperture (79) and by screwing nut member (51) or nut  
member (59) to screw member (20). Then, the lower plate portion (77) is  
mounted to the upper plate portion (78) via the hinge arrangement, i.e., the  
50 male hinge element (505) and the female hinge element (506). To suit patients  
with different anthropometric dimensions of femur neck, both parts of pressure



5 plate (67), the upper plate portion (69) and the lower plate portion (68) are  
matched within a certain range of angular and/or spatial positions by means of  
10 the apertures (86) and corresponding articulating pin, and this is performed  
until pressure plate (76) tightly fits to femur undertrochanter area (6). Then, the  
upper plate portion (78) and the lower plate portion (77) are rigidly fixed  
15 together in this position by screw device (84). Then lower plate portion (77) is  
rigidly mounted, by means of nails and/or wood screws to the external surface  
of femur undertrochanter area (6) via apertures (503), which are preferably in  
20 staggered arrangement as illustrated in Figure 16 to provide more reliable  
attachment of pressure plate (76) to femur undertrochanter area (6). Proximal  
surfaces, (81) and (82) of the pressure plate (76) have profiles complementary  
25 in relation to the adjacent external surface of femur undertrochanter area (6) to  
provide better fit therebetween.

30 Referring to Figures 19 to 25 and 50, the third embodiment of the pressure  
plate (87) is mounted in a similar manner as for the said first embodiment (67)  
35 and said second embodiment (76), *mutatis mutandis*.

Thus, the upper plate portion (87) is rigidly attached to the distal end of screw  
40 member (20) via one aperture (90) and by screwing nut member (51) or nut  
member (59) to screw member (20). Then, the lower plate portion (88) is  
mounted to the upper plate portion (89) via the hinge arrangement, i.e., the  
45 male hinge element (510) and the female hinge element (511). To suit patients  
with different anthropometric dimensions of femur neck, both parts of pressure  
plate (87), the upper plate portion (89) and the lower plate portion (88) are  
50 matched within a certain range of angular and/or spatial positions by means of  
the apertures (95) and corresponding articulating pin, and this is performed

5 until pressure plate (87) tightly fits to femur undertrochanter area (6). Then, the  
upper plate portion (89) and the lower plate portion (88) are rigidly fixed  
10 together in this position by screw device via aperture (90'). Then lower plate  
portion (88) is rigidly mounted, by means of nails and/or wood screws to the  
external surface of femur undertrochanter area (6) via apertures (509), which  
15 are preferably in staggered arrangement as illustrated in Figure 19 to provide  
more reliable attachment of pressure plate (87) to femur undertrochanter area  
(6). Proximal surfaces, (92) and (93) of the pressure plate (87) have profiles  
20 complementary in relation to the adjacent external surface of femur  
undertrochanter area (6) to provide better fit therebetween.

25 In this embodiment, the upper plate portion (89) is designed to be mountable  
onto the lower plate portion (88) in any one of two opposed orientations, in  
order to increase the versatility of the pressure plate (87). Thus, under certain  
conditions, particularly relating to the specific anthropometric dimensions of  
30 particular patients, the said upper plate portion (89) may be turned around by  
180°, and connected to the screw member (20) via aperture (90') instead of  
aperture (90), to achieve tighter fit to femur undertrochanter area (6).  
35

40 Referring to Figures 25 to 31 and 51, the fourth embodiment of the pressure  
plate (96) is mounted in a similar manner as for the said first embodiment (67),  
second embodiment (76) and third embodiment (87), *mutatis mutandis*.

45 Thus, the upper plate portion (98) is rigidly attached to the distal end of screw  
member (20) via aperture (99) and by screwing nut member (51) or nut  
member (59) to screw member (20). Then, the lower plate portion (97) is  
50 mounted to the upper plate portion (98) via the curved lower end (530) and  
block (520). To suit patients with different anthropometric dimensions of femur  
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5 neck, both parts of pressure plate (96), the upper plate portion (98) and the  
lower plate portion (97) are matched within a certain range of angular and/or  
10 spatial positions by means of rotating and/or translating the shoulders (525)  
with respect to the distal portion (526) of block (520). Preferably at least one  
screw device (104) is partially engaged in said block (520) to facilitate this  
15 procedure, which is performed until pressure plate (96) tightly fits to femur  
undertrochanter area (6). Then, the upper plate portion (98) and the lower plate  
portion (97) are rigidly fixed together in this position by a pair of screw  
20 devices (104). Then lower plate portion (97) is rigidly mounted, by means of  
nails and/or wood screws to the external surface of femur undertrochanter area  
(6) via apertures (105), which are preferably in staggered arrangement as  
25 illustrated in Figure 29 to provide more reliable attachment of pressure plate  
(96) to femur undertrochanter area (6). Proximal surfaces, (101) and (102) of  
the pressure plate (96) have profiles complementary in relation to the adjacent  
30 external surface of femur undertrochanter area (6) to provide better fit  
therebetween.

35 Similarly, said pressure plate (400), in particular the first, second, third and  
fourth embodiments thereof, (67), (76), (87) and (96) respectively, may be  
40 adapted for mounting to a femur in conjunction with a regular femur screw or  
nail instead of said device (200) using a similar procedure as described above  
with reference to Figures 48 to 51, *mutatis mutandis*.

45  
Where necessary, screw member (20) may be removed after the union of femur  
50 neck parts. For this purpose the above procedure is carried out in the reverse  
order. First thrust member (64) is removed, then, by turning axial threaded stub

5 (62), the arms (46) of antimigration device (300) are moved inside axial cavity<sup>55</sup> (35), opening thereby its release tabs (48) and retracting them into slits (39).  
10 Thereafter, by means of special wrench nut member (51) is unscrewed and pressure plate (400) is removed (if it has been mounted). This is performed in an order reverse to that of setting the screw member (20). Thereupon screw member (20) is removed from the femur neck. To facilitate the removal of  
15 screw member (20), the proximal end of screw thread (31) is formed as a screw tap, which is thus used for cutting off excrescences of bone tissue which have grown in the bore in the femur neck wherefrom screw member (20) is  
20 removed. The removal of screw member (20) is typically performed under periodic X-ray monitoring.

25 Each component of the device (200), including screw member (20), nut member (51) (or nut member (59), as necessary), antimigration device (300), extension member (24) and pressure plate (400), is made from a medically  
30 compatible material, typically titanium, for example.

35 Application of the claimed device for femur neck osteosynthesis provides accurate and secure matching of bone fragments in compression during the whole period of the fracture union. Further, the duration of surgical interference is essentially reduced and traumatization of endosteum and bone  
40 marrow of the femur head and neck is insignificant. The claimed device is suitable for compression treatment of all kinds of femur neck fractures, including medial fractures, such as subcapital fracture and lateral fractures,  
45 including undertrochanter fractures. And finally the claimed device is adapted to any anthropological parameters of different patients, easily mounted and, when necessary, easily removed.

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5 Thus, screw member (20) in combination with nut member (51) (or nut  
member (59), as necessary), antimigration device (300), optionally extension  
10 member (24) and pressure plate (400) form a unifiable integrated spatial  
system which provides reliable compression fixing of bone fragments for  
patients having different anthropometric dimensions and for any kind of femur  
15 neck fractures, including undertrochanter, intertrochanter and transtrochanter  
lateral fractures. Thus, the present invention provides a universal means for  
reliable osteosynthesis of all known femur neck fractures.

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While in the foregoing description describes in detail only a few specific  
embodiments of the invention, it will be understood by those skilled in the art  
25 that the invention is not limited thereto and that other variations in form and  
details may be possible without departing from the scope and spirit of the  
invention herein disclosed.  
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## Claims

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**Claims: -**

1. A device for fixating a fractured femur, comprising :-

(a) an elongated screw member adapted for penetrating into at least the neck portion of a femur, comprising :-

a proximal portion comprising a first cylindrical member having an external first screw thread adapted for distal compressive engagement with bony tissue in particular within the femur;

a distal portion comprising a second cylindrical member having an internal cavity and a substantially open distal end, and at least one lateral portal for enabling communication between said cavity and an outside of said second cylindrical member;

an antimigration device accommodated in said cavity and comprising at least one anchoring means having gripping means, said at least one anchoring means being selectively extendable such that said gripping means extends to said outside of said distal portion via a corresponding one of said at least one portal, said gripping means being adapted for anchoring said antimigration device within bony tissue when said gripping means is brought into engagement therewith;

and

(b) compression means releasably engageable with said distal portion of said screw member and selectively axially displaceable with respect thereto, said compression means having a proximal pressure face;

characterised in that said antimigration device comprises axially movable fixation means for selectively setting and fixing the relative axial position of said gripping means with respect to said second cylindrical member.

- 5 2. A device for fixating a fractured femur as claimed in claim 1, wherein said  
first cylindrical member is integrally joined to said second cylindrical  
10 member.
3. A device for fixating a fractured femur as claimed in claim 1, wherein said  
15 first screw thread comprises an external diameter substantially similar to an  
external diameter of said second cylindrical member.
4. A device for fixating a fractured femur as claimed in claim 1, wherein said  
20 first cylindrical member comprises an axial lumen extending therethrough  
and having a proximal opening in said first cylindrical member and in  
communication with said cavity, said axial lumen and said cavity being of a  
25 size sufficient to enable a suitable alignment needle to be accommodated  
therein.
5. A device for fixating a fractured femur as claimed in claim 3, wherein at  
30 least the proximal end of said first screw thread is self-taping with respect  
to bony tissue.
6. A device as claimed in claim 5, wherein said at least proximal end of said  
35 screw thread comprises a plurality of circumferentially spaced radial slots to  
provide portions of said screw thread in the form of blade-like elements  
separated by said radial slots, said blade like elements having leading edges  
40 adapted for taping into bony tissue.
7. A device as claimed in claim 3, wherein said first screw thread comprises at  
45 least distal thread surfaces adapted for compressive engagement with bony  
tissue in response to a distal longitudinal force applied to said screw  
50 member.
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- 5 8. A device as claimed in claim 7, wherein said distal thread surfaces of said  
first screw thread comprises a distal tilt angle of between about 2° to about  
10 4°.
- 15 9. A device for fixating a fractured femur as claimed in claim 3, wherein said  
first screw thread comprises proximal thread surfaces having a proximal tilt  
angle of between about 30° to about 35°.
- 20 10. A device for fixating a fractured femur as claimed in claim 1, wherein  
said proximal portion of said screw member comprises at least one  
longitudinal groove for facilitating transportation of bony tissue debris from  
the proximal end to the distal end of said first cylindrical member during  
25 implantation of said device.
- 30 11. A device for fixating a fractured femur as claimed in claim 1, wherein  
said at least one portal is in the form of a longitudinal slit along the  
cylindrical wall of said second cylindrical member.
- 35 12. A device for fixating a fractured femur as claimed in claim 1, wherein  
said antimigration device comprises a proximally disposed ring,  
substantially coaxial with said second cylindrical member, and wherein said  
at least one anchoring means is in the form of a corresponding resilient arm  
40 cantilevered from said ring and extending substantially distally therefrom,  
said arm having a corresponding said at least one gripping means at the free  
distal end thereof, said antimigration device further comprising actuation  
45 means for reversibly extending said gripping means in a lateral direction .
- 50 13. A device for fixating a fractured femur as claimed in claim 12, wherein  
said actuation means comprises an axially movable thrust element having an  
external second screw thread complementary to and engaged with an  
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5 internal third screw thread comprised at least in a distal portion of said  
cavity of said second cylindrical member, wherein a proximal end of said  
10 thrust element comprises a convex conical surface, said conical surface  
adapted to abut against and urge said free end of said at least one arm  
laterally outwards in response to an axial translation in the proximal  
15 direction by said thrust element.

14. A device for fixating a fractured femur as claimed in claim 13, wherein  
said thrust element comprises a substantially diametrical slot on the distal  
20 end thereof for engaging with an external complementary first tool so as to  
enable said thrust member to be axially displaced within said cavity by  
means of corresponding rotation of said first tool.

15. A device for fixating a fractured femur as claimed in claim 12, wherein  
said gripping means comprises an externally facing tab having at least one  
30 bone-engaging edge.

16. A device for fixating a fractured femur as claimed in claim 15, wherein  
said bone-engaging edge is serrated.

17. A device for fixating a fractured femur as claimed in claim 15, wherein  
said at least one arm is biased such that said tab does not significantly  
40 protrude from said corresponding at least one portal when said actuation  
means is disengaged from said anchoring means.

18. A device for fixating a femur as claimed in claim 12, wherein said  
45 axially movable fixation means for selectively setting and fixing the relative  
axial position of said gripping means with respect to said second cylindrical  
member comprises a stub member engaged with and axially movable with  
50 respect to said ring member, said stub member having a proximal end for

rotatably abutting against a proximal end of said cavity, and a distal end axially spaced from said engagement means.

19. A device for fixating a femur as claimed in claim 18, wherein said stub member comprises an external fourth screw thread complementary to and engaged with an internal fifth screw thread comprised in said second ring member.
20. A device for fixating a femur as claimed in claim 19, wherein said distal end of said stub member comprises a substantially diametrical slot for engaging with an external complementary second tool so as to enable said ring member to be axially displaced respect to said stub member by means of corresponding rotation of said second tool.
21. A device for fixating a fractured femur as claimed in claim 1, wherein said compression means comprises an axially movable first nut element having an internal sixth screw thread complementary to and engaged with an external seventh screw thread comprised at least in a distal portion of said second cylindrical member.
22. A device for fixating a fractured femur as claimed in claim 21, wherein a proximal end of said first nut element comprises a rounded annular edge.
23. A device for fixating a fractured femur as claimed in claim 21, wherein said first nut element comprises a pair of substantially diametrically opposed recesses on the distal end thereof for engaging with an external complementary third tool so as to enable said first nut element to be axially displaced within with respect to said screw member by means of corresponding rotation of said third tool.

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24. A device for fixating a fractured femur as claimed in claim 1, wherein said second cylindrical member comprises a pair of substantially diametrically opposed radial slots on the distal end thereof for engaging with an external complementary fourth tool so as to enable said screw member to be axially advanced into a femur by means of corresponding rotation of said fourth tool.

25. A device for fixating a fractured femur as claimed in claim 1, further comprising an axially engageable longitudinal extension member for effectively increasing the axial length of said screw member, wherein at least a proximal portion of said extension member comprises an external second screw thread complementary to and engaged with an internal third screw thread comprised at least in a distal portion of said cavity of said second cylindrical member, and wherein said compression means is releasably engageable with a distal portion of said extension member and selectively axially displaceable with respect thereto.

26. A device for fixating a fractured femur as claimed in claim 25, wherein said extension member is a tubular member having an external diameter substantially complementary to the internal diameter of said distal end of said screw member.

27. A device for fixating a fractured femur as claimed in claim 26, wherein said compression means comprises an axially movable second nut element having an internal eighth screw thread complementary to and engaged with said external second screw thread comprised in a distal portion of said extension member.

28. A device for fixating a fractured femur as claimed in claim 27, wherein a proximal end of said second nut element comprises a rounded annular edge.

- 5 29. A device for fixating a fractured femur as claimed in claim 27, wherein  
said second nut element comprises a pair of substantially diametrically  
10 opposed recesses on the distal end thereof for engaging with an external  
complementary fifth tool so as to enable said second nut element to be  
axially displaced within with respect to said extension member by means of  
15 corresponding rotation of said fifth tool.
- 20 30. A device for fixating a fractured femur as claimed in claim 26, wherein  
said extension member comprises a pair of substantially diametrically  
opposed radial slots on the distal end thereof for engaging with an external  
25 complementary sixth tool so as to enable said extension member to be  
axially displaced with respect to said screw member by means of  
corresponding rotation of said sixth tool.
- 30 31. A device for fixating a fractured femur as claimed in claim 25, wherein  
said extension member is a stepped tubular member having a proximal  
portion and a distal portion, wherein said proximal portion of said tubular  
member comprises an external diameter substantially complementary to the  
35 internal diameter of said distal end of said screw member, and wherein said  
distal portion of said tubular member comprises an external diameter  
substantially equal to the external diameter of said distal end of said screw  
40 member.
- 45 32. A device for fixating a fractured femur as claimed in claim 31, wherein  
said compression means comprises an axially movable first nut element  
having an internal sixth screw thread complementary to and engaged with  
an external seventh screw thread comprised in at least a distal portion of  
50 said extension member.
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- 5 33. A device for fixating a fractured femur as claimed in claim 32, wherein a proximal end of said second nut element comprises a rounded annular edge.
- 10 34. A device for fixating a fractured femur as claimed in claim 32, wherein said first nut element comprises a pair of substantially diametrically opposed recesses on the distal end thereof for engaging with an external complementary third tool so as to enable said first nut element to be axially displaced within with respect to said extension member by means of
- 15 corresponding rotation of said third tool.
- 20 35. A device for fixating a fractured femur as claimed in claim 32, wherein said extension member comprises a pair of substantially diametrically opposed radial slots on the distal end thereof for engaging with an external complementary fourth tool so as to enable said extension member to be axially displaced with respect to said screw member by means of
- 25 corresponding rotation of said fourth tool.
- 30 36. A device for fixating a fractured femur as claimed in any one of claims 1 to 35, wherein further comprising a locking plate for further securing said screw member to a femur, said locking plate characterised in having an upper plate portion, a lower plate portion and adjusting means for adjusting
- 35 at least one of the relative angular disposition and the relative linear displacement between said upper plate portion and said lower plate portion, and wherein said upper plate portion is adapted for rigid securement to said screw member via said compression means, and wherein said lower plate
- 40 portion is adapted for rigid securement with respect to a distal portion of the femur.
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37. A device for fixating a fractured femur as claimed in claim 36, wherein said lower plate portion comprises a proximal surface having a profile complementary to a lower portion of said distal portion of the femur.

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38. A device for fixating a fractured femur as claimed in claim 37, wherein said lower plate portion may be rigidly secured to said distal portion of said femur by at least one suitable screw via a corresponding at least one aperture comprised in said lower plate portion.

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39. A device for fixating a fractured femur as claimed in claim 36, wherein said upper plate portion comprises a proximal surface having a profile complementary to an upper portion of said distal portion of the femur.

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40. A device for fixating a fractured femur as claimed in claim 36, wherein said upper plate portion comprises a first aperture adapted for securely engaging with a distal end of said device, and wherein said compression means compressively engages proximally with a distal end of said femur via said upper plate portion.

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41. A device for fixating a fractured femur as claimed in claim 40, further comprising fixing means for fixing at least one of the relative angular disposition and the relative linear displacement between said upper plate portion and said lower plate portion.

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42. A device for fixating a fractured femur as claimed in claim 40, wherein said compression means is in the form of a nut member having a rounded proximal annular edge, said first aperture having a flared distal entry complementary shaped to said rounded proximal annular edge.

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43. A device for fixating a fractured femur as claimed in claim 41, wherein said adjustment means comprises a hinge arrangement having a first hinge

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5 element comprised at an upper end of said lower plate portion and a  
cooperating second hinge element comprised in said upper plate portion  
intermediate an upper end and lower end of said upper plate portion, said  
10 upper end of said upper plate portion comprising said first aperture and said  
lower end of said upper plate portion comprising said fixing means.

15 44. A device for fixating a fractured femur as claimed in claim 43, wherein  
said fixing means comprises a at least one screw device having a first  
threaded portion engaged with and adapted for axial displacement with  
20 respect to a complementary threaded second aperture comprised in said  
lower end of said upper plate portion, said threaded portion having a  
proximal end rotatably engaged with said lower plate portion, and wherein  
25 said at least one screw device further comprises an actuating portion so as  
to enable said at least one screw device to be axially displaced with respect  
to said upper plate portion by suitable means.

30 45. A device for fixating a fractured femur as claimed in claim 41, wherein  
said adjustment means comprises a linearly adjustable hinge arrangement  
having a first male hinge element comprised at an upper end of said lower  
35 plate portion and a cooperating second female hinge element comprised in  
said upper plate portion intermediate an upper end and lower end of said  
upper plate portion, said upper end of said upper plate portion comprising  
40 said first aperture and said lower end of said upper plate portion comprising  
said fixing means, wherein said female hinge element comprises a plurality  
45 of lateral apertures for selectively articulately engaging said male element  
in one of a corresponding plurality of relative linear relationships with  
respect to said lower plate portion via an articulating pin.

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46. A device for fixating a fractured femur as claimed in claim 45, wherein said fixing means comprises a at least one screw device having a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded second aperture comprised in said lower end of said upper plate portion, said threaded portion having a proximal end for abutting against a distal surface of said lower plate portion, and wherein said at least one screw device further comprises an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said upper plate portion by suitable means.

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47. A device for fixating a fractured femur as claimed in claim 41, wherein said adjustment means comprises a linearly adjustable hinge arrangement having a first male hinge element comprised at an upper end of said lower plate portion and a cooperating second female hinge element comprised in said upper plate portion intermediate an upper end and lower end of said upper plate portion, wherein said female hinge element comprises a plurality of lateral apertures for selectively articulately engaging said male element in one of a corresponding plurality of relative linear relationships with respect to said lower plate portion via an articulating pin, wherein said upper end of said upper plate portion comprises at least one said first aperture, and wherein said lower end of said upper plate portion comprises at least one said second aperture, said fixing means being associated with any one of said at least one second aperture.

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48. A device for fixating a fractured femur as claimed in claim 47, wherein said upper plate portion may be selectively engaged with respect to the said lower plate portion in one of a first or a second orientation corresponding to having said upper end or said lower end respectively, of said upper plate portion uppermost, wherein said at least one second apertures are

5 substantially identical to said at least one first apertures, and wherein in said  
second orientation, one said second aperture is associated with said device  
10 and one said first aperture is associated with said fixing means.

15 49. A device for fixating a fractured femur as claimed in claim 48, wherein  
said fixing means comprises a at least one screw device having a first  
threaded portion engaged with and adapted for axial displacement with  
respect to complementary threaded said second aperture comprised in said  
20 lower end or in said upper end of said upper plate portion, when said upper  
plate element is in said first or said second orientation, respectively, said  
threaded portion having a proximal end for abutting against a distal surface  
of said lower plate portion, and wherein said at least one screw device  
25 further comprises an actuating portion so as to enable said at least one  
screw device to be axially displaced with respect to said upper plate portion  
by suitable means.

30 50. A device for fixating a fractured femur as claimed in claim 48, wherein  
said upper plate portion has a substantially S-shaped transverse  
cross-section.

35 51. A device for fixating a fractured femur as claimed in claim 41, wherein  
said adjustment means is in the form of a curved lower end comprised in  
40 said upper plate portion, said slot having laterally disposed shoulders  
parallel thereto and cooperating with a male reaction block comprised an  
upper end of said lower plate portion, wherein said curved lower end and  
45 said block comprising suitable profiles such as to enable the area of contact  
between said lower end and said block to be adjusted such as to provide at  
least one of a range of relative angular dispositions and a range of relative  
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linear displacements between said upper plate portion and said lower plate portion.

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52. A device for fixating a fractured femur as claimed in claim 51, wherein said fixing means comprises at least one screw device for clamping said upper plate portion to said lower plate portion, said at least one screw device having a first threaded portion engaged with and adapted for axial displacement with respect to a complementary threaded third aperture comprised in said block of said lower plate portion, and wherein said at least one screw device further comprises a thrust surface for clamping contact with a distal surface of said lower portion, and an actuating portion so as to enable said at least one screw device to be axially displaced with respect to said lower plate portion by suitable means.

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53. A device for fixating a fractured femur as claimed in claim 52, wherein said fixing means comprises two said screw devices disposed along the length of said block.

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54. A device for fixating a fractured femur as claimed in claim 51, wherein said slot has an open lower end.

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55. A device for fixating a fractured femur as claimed in any one of claims 1 to 35, wherein said pressure face of said compression means is adapted for selectively compressively engaging proximally with a distal end of said femur.

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56. A device for fixating a fractured femur as claimed in claim 36, wherein said pressure face of said compression means is adapted for selectively compressively engaging proximally with a distal end of said femur via said upper plate portion.

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57. A device for fixating a fractured femur as claimed in any one of claims 37 to 54, wherein said pressure face of said compression means is adapted for selectively compressively engaging proximally with a distal end of said femur via said upper plate portion.

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58. A device for fixating a fractured femur, substantially as herein described with reference to the accompanying figures.

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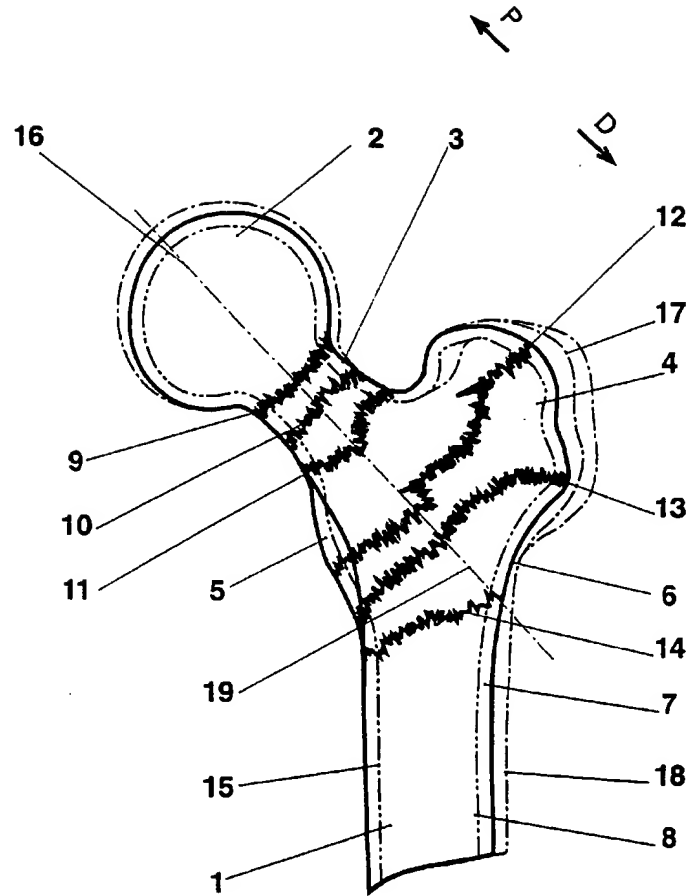


FIG.1

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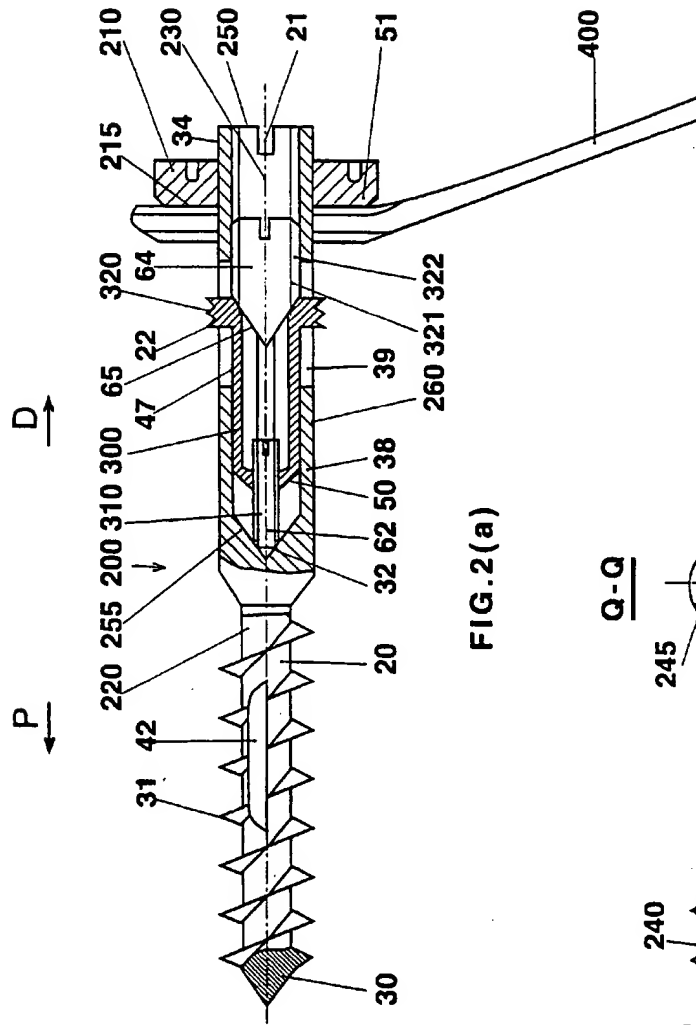


FIG. 2(a)

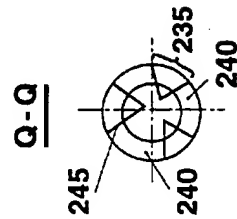


FIG. 2(c)

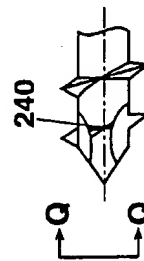
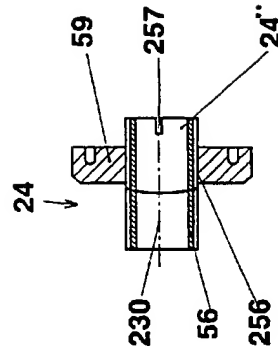
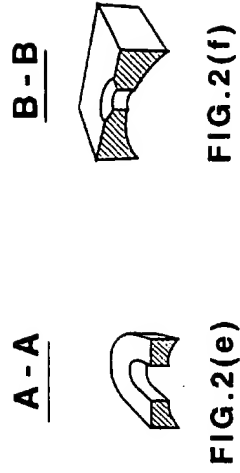
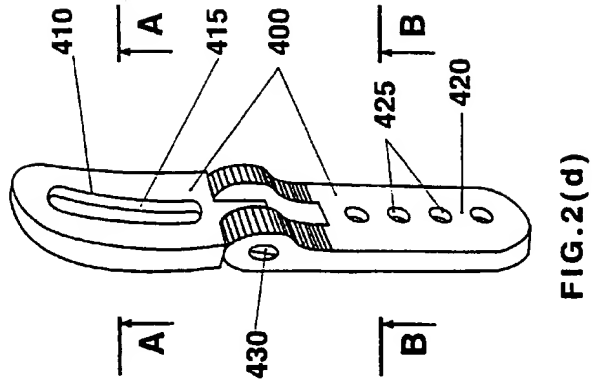
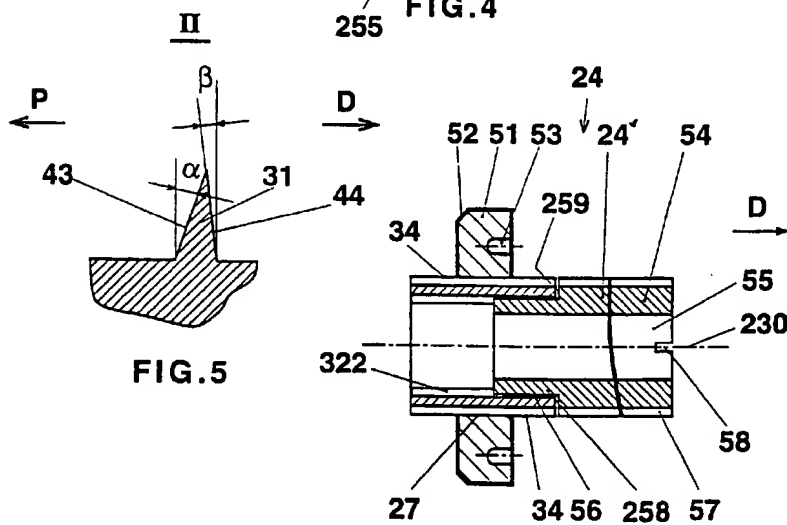
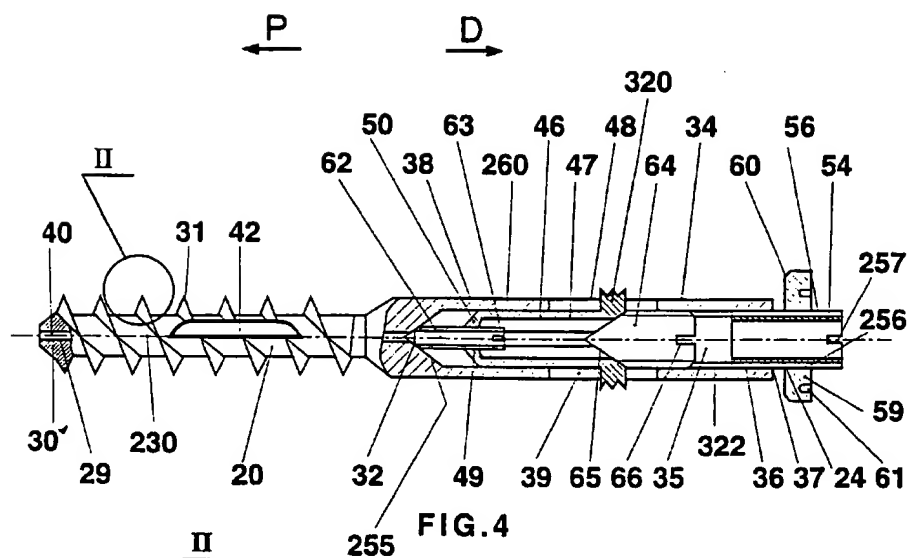


FIG. 2(b)

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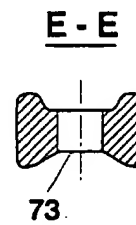
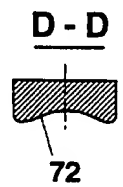
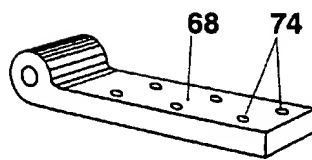
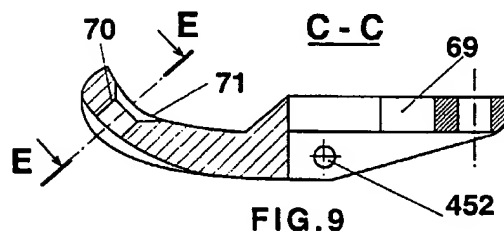
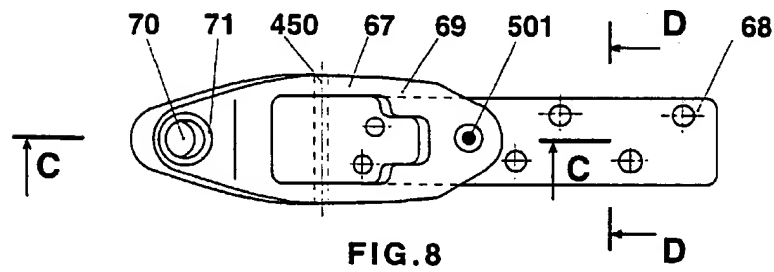
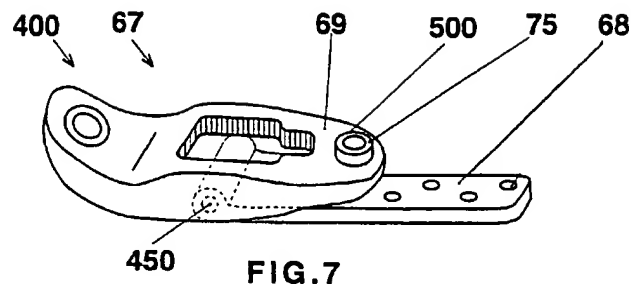


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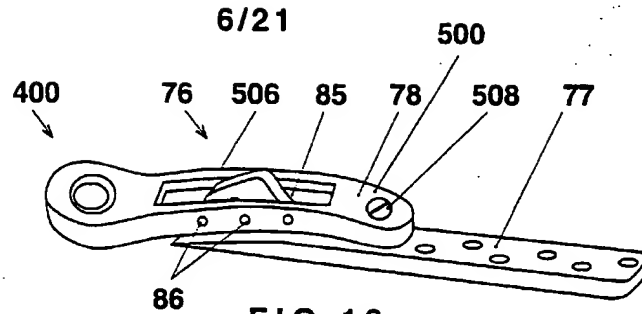


FIG. 13

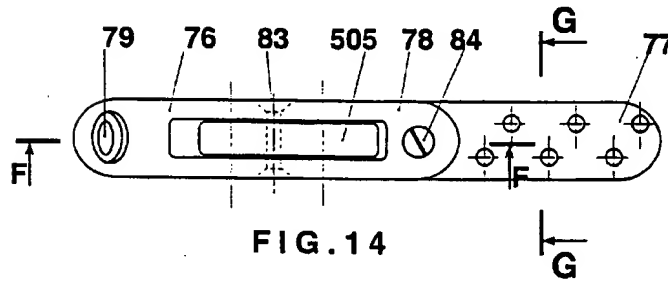


FIG. 14

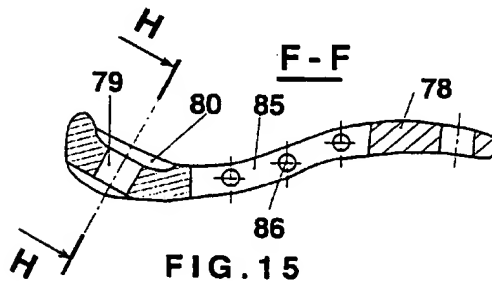


FIG. 15

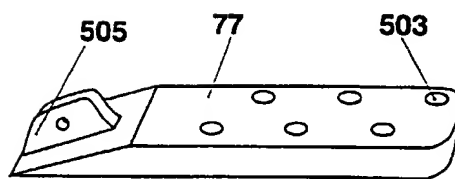


FIG. 16

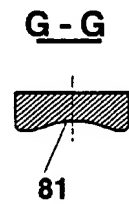


FIG. 17

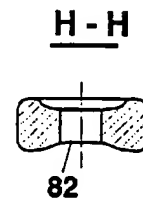


FIG. 18

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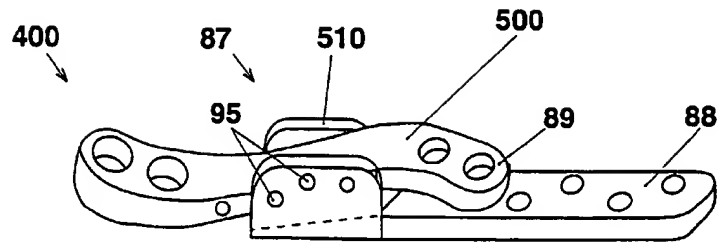


FIG. 19

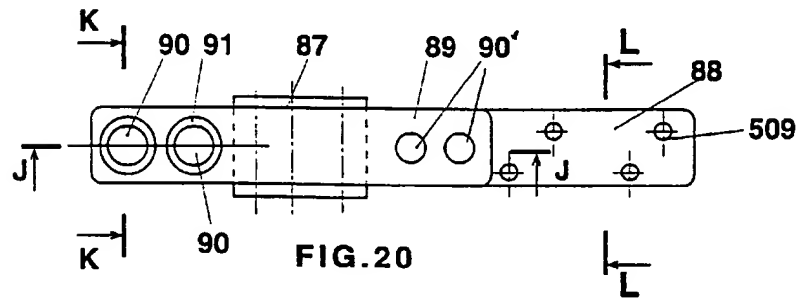


FIG. 20

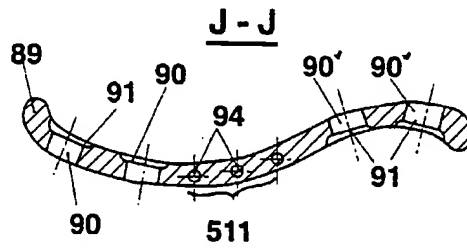


FIG. 21

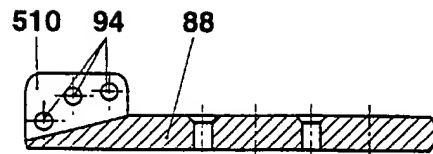


FIG. 22

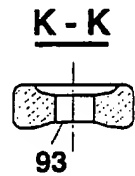


FIG. 23

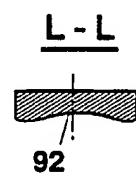


FIG. 24

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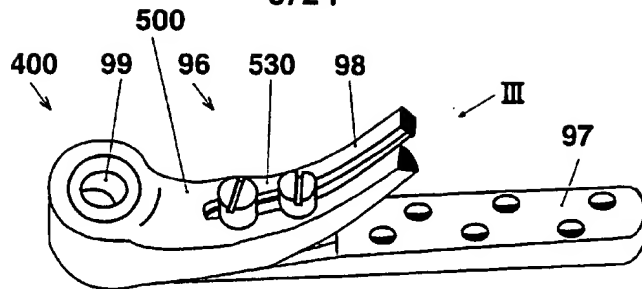


FIG. 25

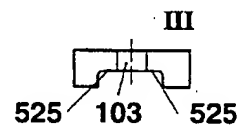


FIG. 26

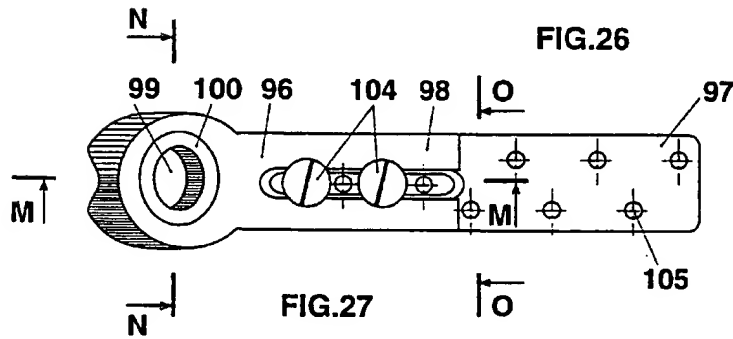


FIG. 27

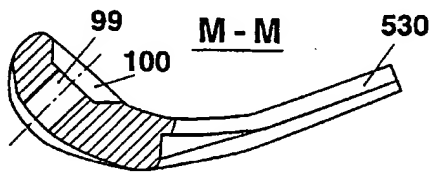


FIG. 28

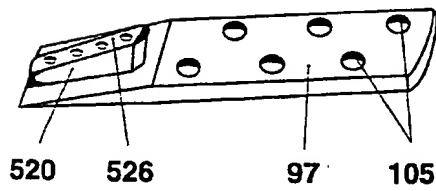


FIG. 29

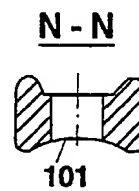


FIG. 30

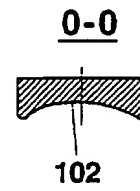
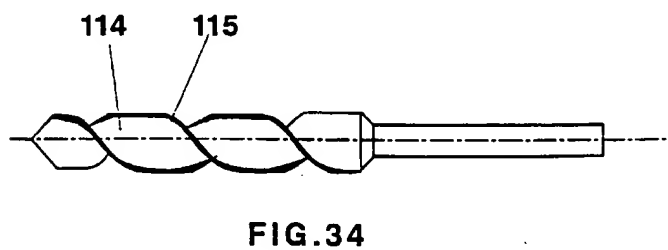
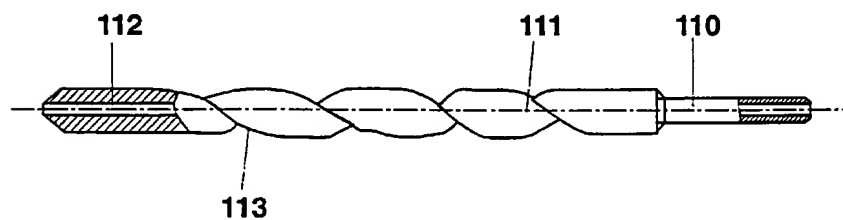
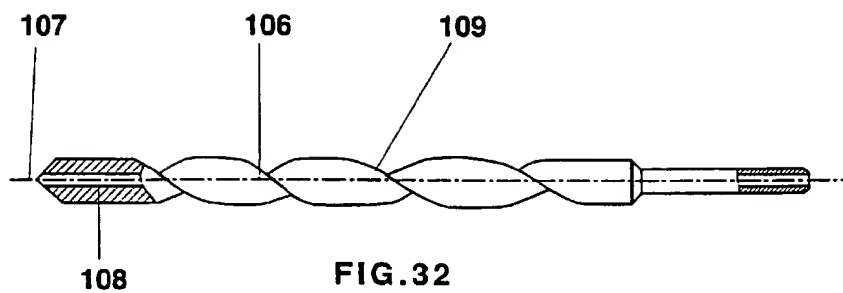


FIG. 31

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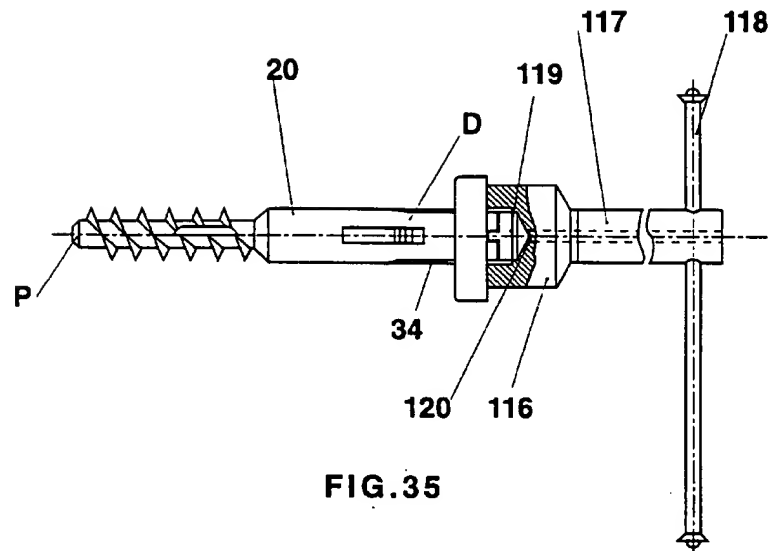


FIG. 35

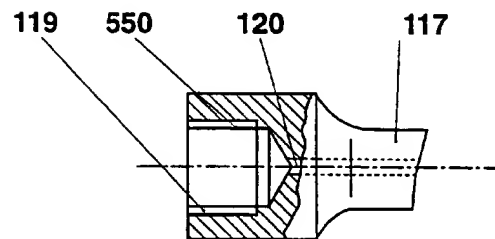
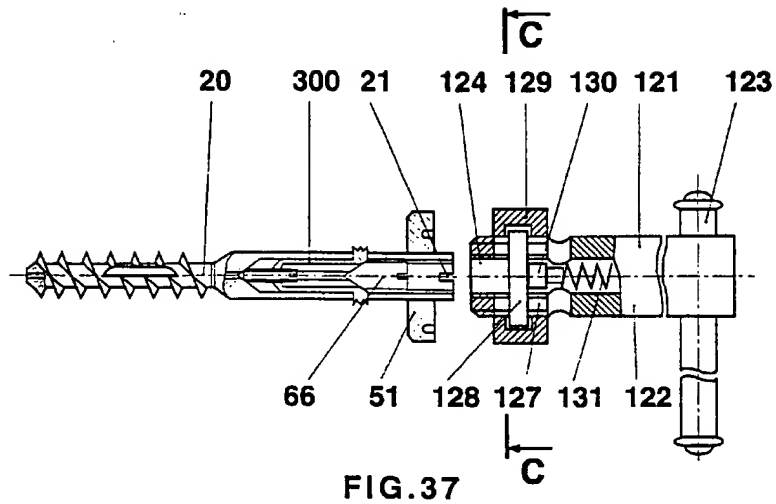
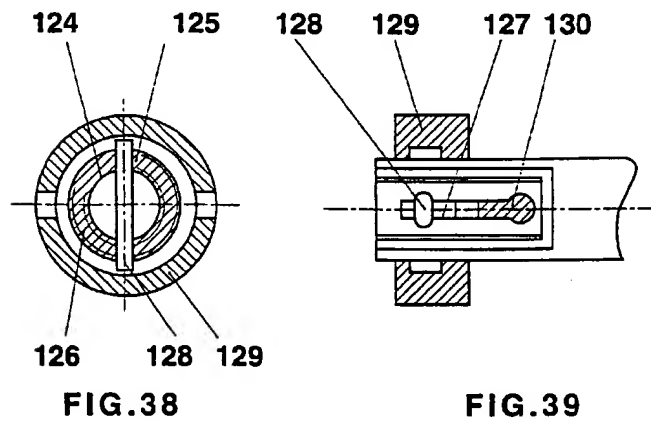


FIG. 36

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C - C



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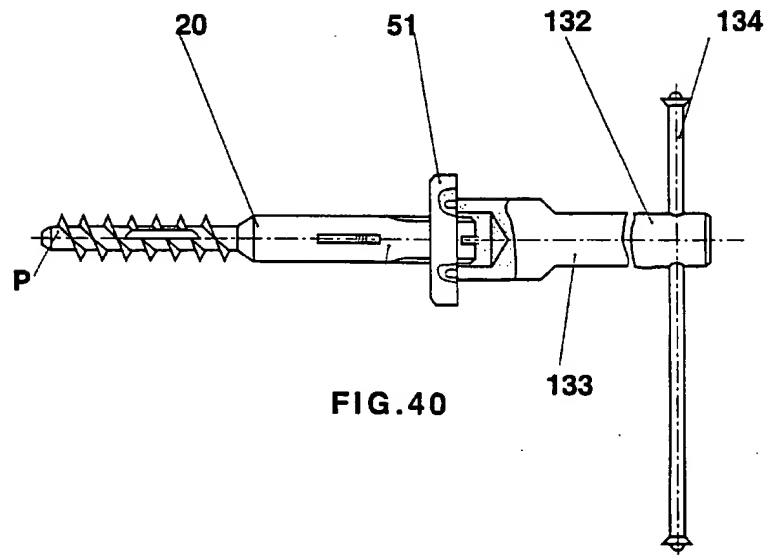


FIG. 40

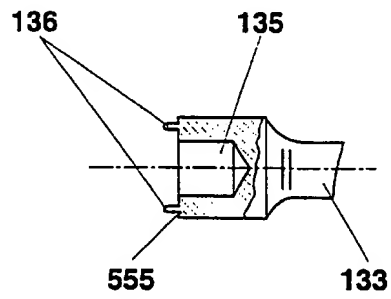


FIG. 41



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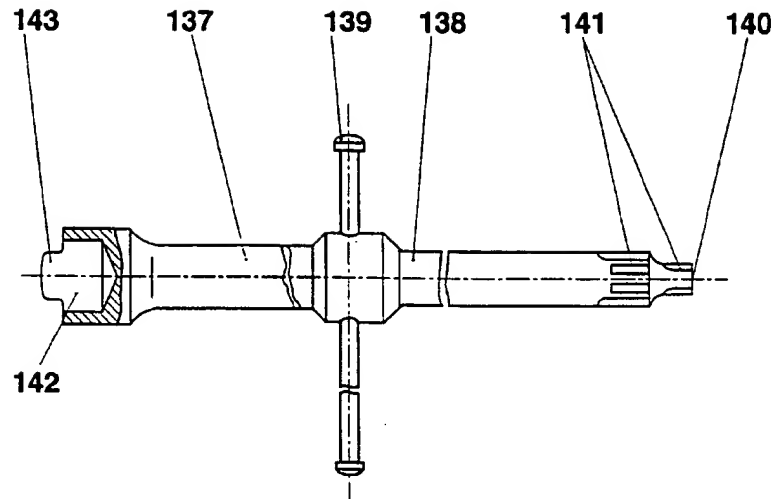


FIG. 42

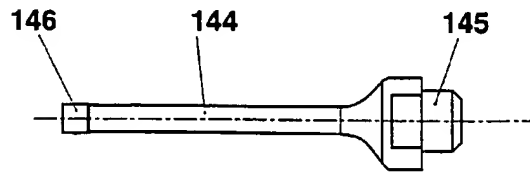


FIG. 43

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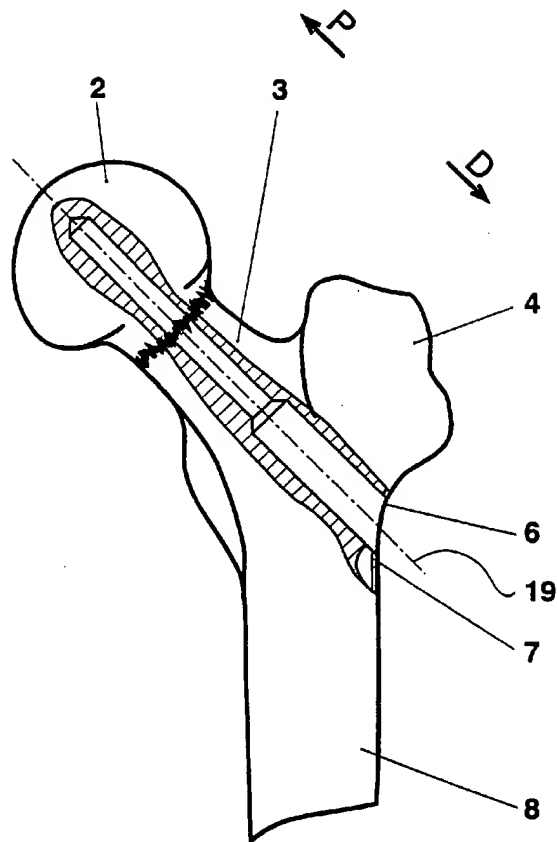


FIG. 44

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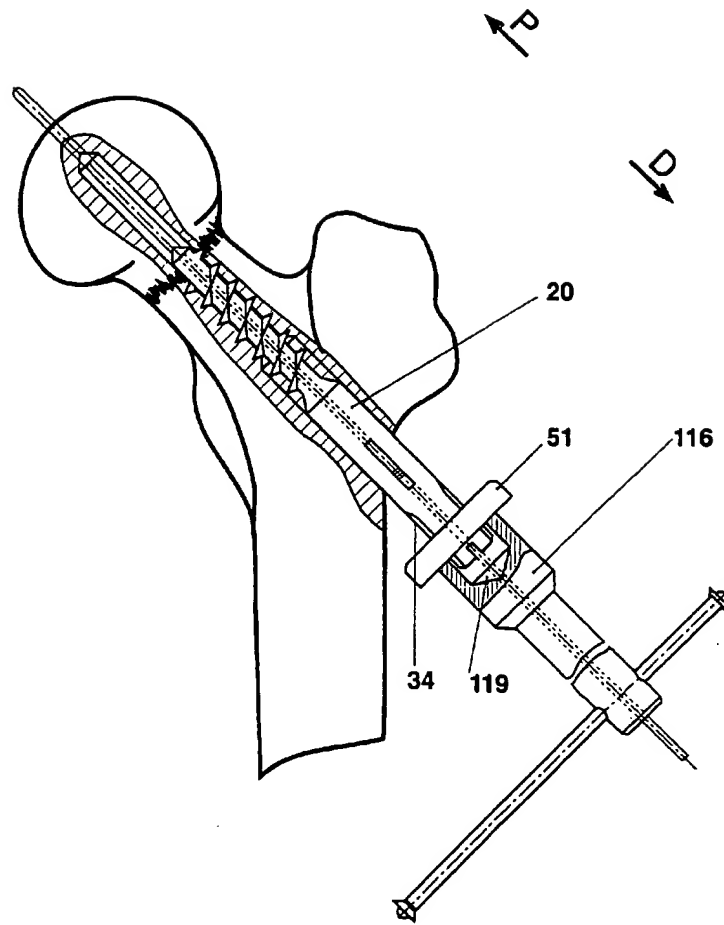


FIG. 45

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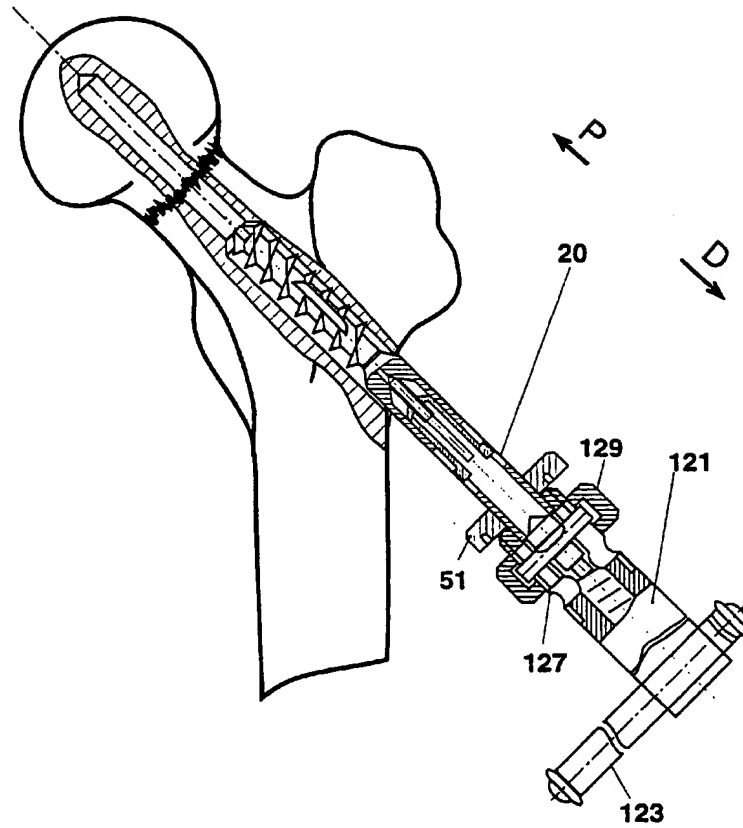


FIG.46

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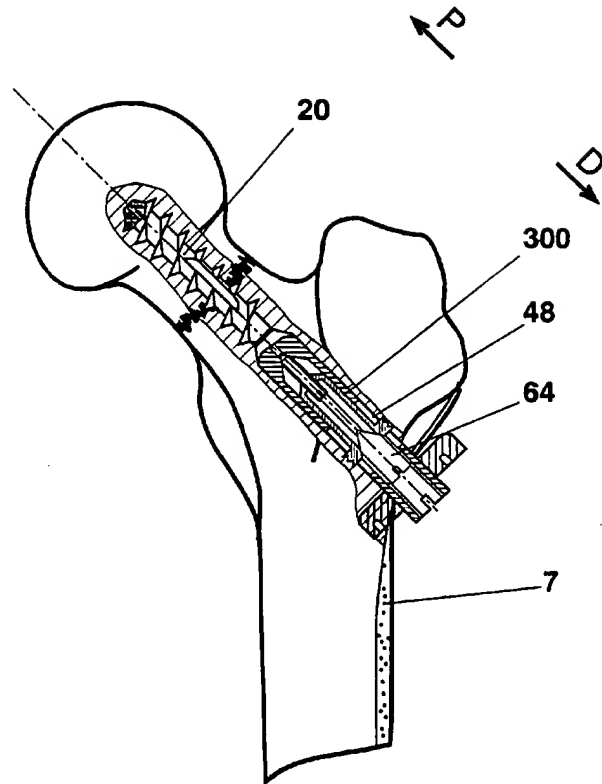


FIG. 47

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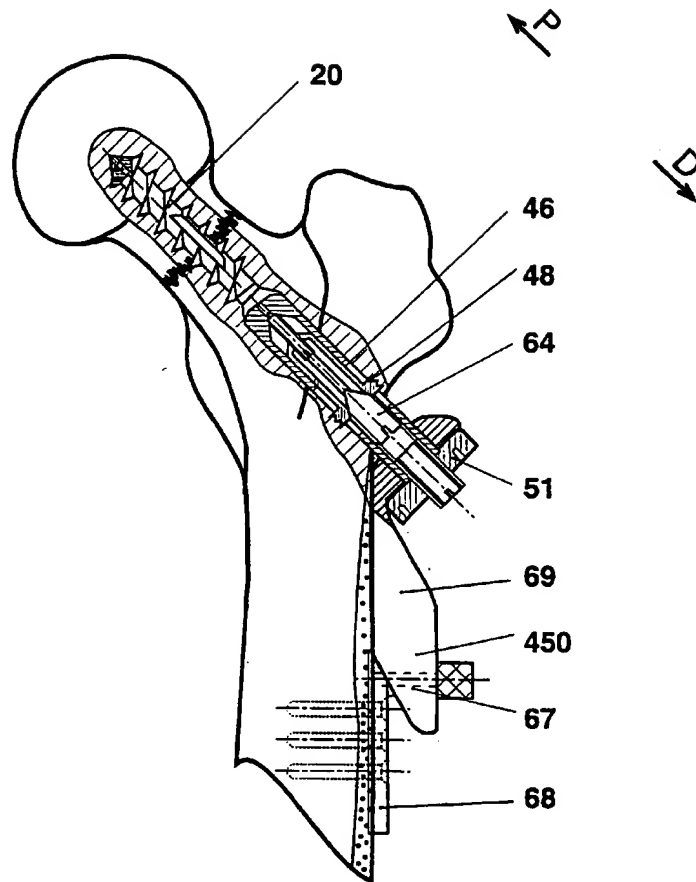


FIG. 48

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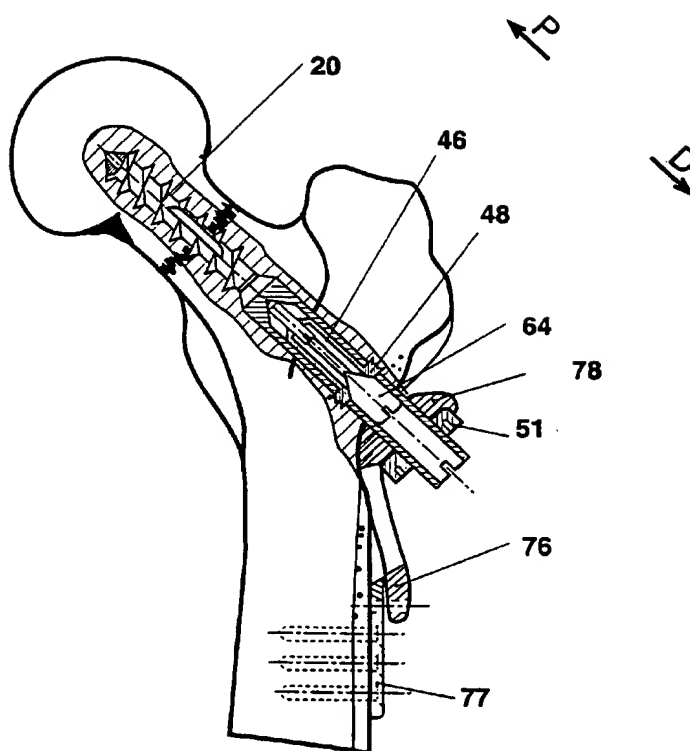


FIG.49

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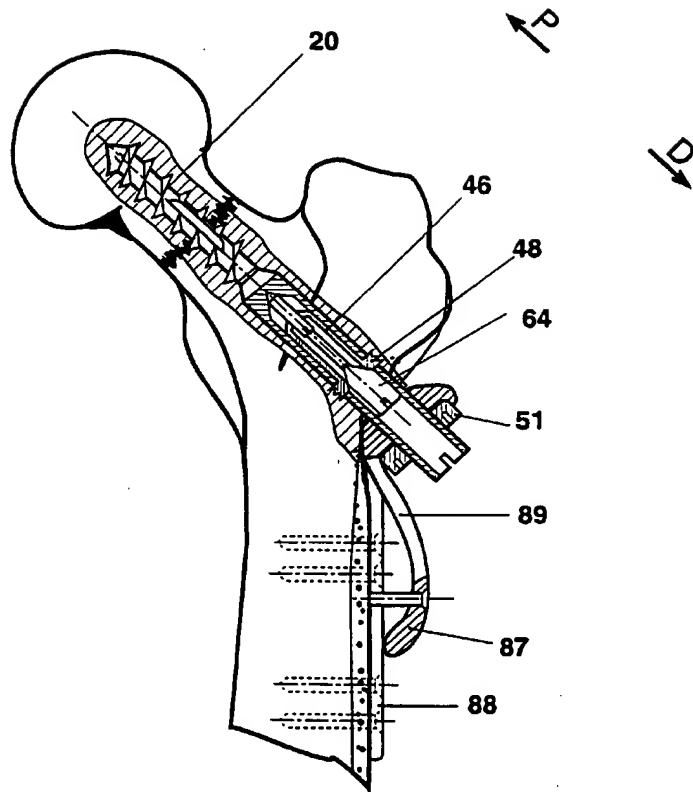


FIG. 50



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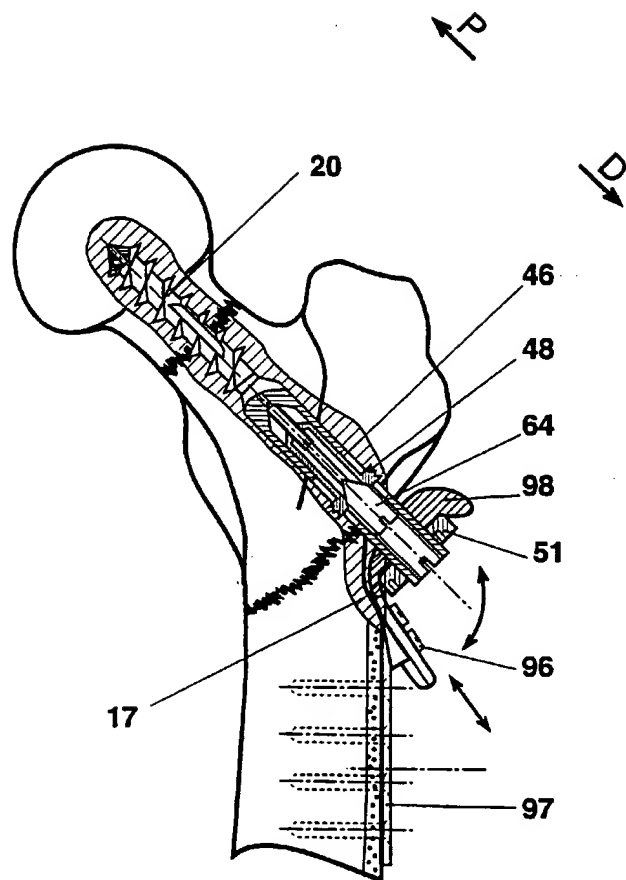


FIG. 51

# INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/IL 00/00269

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B17/74 A61B17/86 A61B17/72 A61B17/80

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 02105 A (BRAMLET DALE G) 22 January 1998 (1998-01-22)  page 13, line 27 - page 14, line 11 page 15, line 6 - line 21 figures 2,5,6 ---	1,2,4,5, 7,10,12, 14,15, 25,36,58
A	CH 475 754 A (PAUL KLEUSER CHIRURGISCHE INSTRUMENTE UND APPARATE) 31 July 1969 (1969-07-31) column 2, line 17 - line 33; figure 1 ---	1,2,4,5, 7,21,36, 58
A	EP 0 636 346 A (SANTANGELO MASSIMO) 1 February 1995 (1995-02-01) the whole document ---  -/-	1

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☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

13 September 2000

Date of mailing of the international search report

26/09/2000

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# INTERNATIONAL SEARCH REPORT

In. tional Application No

PCT/IL 00/00269

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 437 674 A (KOVACS ERIC ET AL) 1 August 1995 (1995-08-01) column 3, line 26 - line 65; figure 1	1,2,4,5, 7,58
A	US 4 432 358 A (FIXEL IRVING E) 21 February 1984 (1984-02-21) figures 1,2	1-5,8
A	US 4 236 512 A (AGINSKY JACOB) 2 December 1980 (1980-12-02) claim 1; figure 1	1,21,25, 58
A	FR 2 653 660 A (HECHARD PATRICK) 3 May 1991 (1991-05-03) claim 1; figure 5	1

# INTERNATIONAL SEARCH REPORT

Information on patent family members

In ternational Application No

PCT/IL 00/00269

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9802105 A	22-01-1998	US 5976139 A AU 3662597 A EP 0925038 A	02-11-1999 09-02-1998 30-06-1999
CH 475754 A	31-07-1969	NONE	
EP 0636346 A	01-02-1995	JP 7067897 A US 5534004 A US 5759184 A	14-03-1995 09-07-1996 02-06-1998
US 5437674 A	01-08-1995	FR 2695026 A AT 182063 T AU 670456 B AU 4963893 A BR 9305618 A CA 2122017 A DE 69325642 D DE 69325642 T EP 0609425 A ES 2136666 T WO 9404086 A HU 67894 A, B JP 7500520 T NO 941487 A	04-03-1994 15-07-1999 18-07-1996 15-03-1994 02-01-1996 03-03-1994 19-08-1999 06-04-2000 10-08-1994 01-12-1999 03-03-1994 29-05-1995 19-01-1995 22-04-1994
US 4432358 A	21-02-1984	NONE	
US 4236512 A	02-12-1980	NONE	
FR 2653660 A	03-05-1991	FR 2626169 A	28-07-1989